

Exhibit H

Ann M. Weber, M.D.

Page 1

1 IN THE COURT OF COMMON PLEAS
2 PHILADELPHIA COUNTY, PENNSYLVANIA

3 - - -
4 IN RE: PELVIC MESH :
 LITIGATION :
5 ----- :
 PATRICIA L. HAMMONS : MAY TERM, 2013
6 :
 Plaintiff, :
7 :
 v. : NO. 003913
8 :
 ETHICON, INC., et al. :

9
10 - - -
11 September 1, 2015
12 - - -

13 Oral deposition of
14 ANNE M. WEBER, M.D., taken pursuant to
15 notice, was held at the law offices of
16 Kline & Specter, 1525 Locust Street,
17 Philadelphia, Pennsylvania commencing at
18 9:03 a.m., on the above date, before
19 Michelle L. Gray, a Registered
20 Professional Reporter, Certified
 Shorthand Reporter and Notary Public.

21 - - -
22 GOLKOW TECHNOLOGIES, INC.
23 877.370.3377 ph|917.591.5672 fax
24 deps@golkow.com

Ann M. Weber, M.D.

Page 2		Page 4	
1	APPEARANCES:	1	- - -
2		2	I N D E X
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9	Representing the Plaintiff		By Mr. Slater 223
10		7	
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17	Representing the Plaintiff	14	Weber-1 Reliance Materials 9
18		15	Weber-2 Report of Anne M. 22
19	TUCKER ELLIS, LLP		Weber, M.D.
20	BY: MATTHEW P. MORIARTY, ESQUIRE	16	Volume I & II
21	950 Main Avenue, Suite 1100	17	Weber-3 Notice of Deposition 24
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	Representing the Defendants		
	- - -		

Page 3		Page 5	
1	(It is hereby stipulated and	1	- - -
2	agreed by and among counsel that	2	E X H I B I T S (Cont'd.)
3	sealing, filing and certification	3	- - -
4	are waived; and that all	4	
5	objections, except as to the form	5	NO. DESCRIPTION PAGE
6	of questions, be reserved until	6	Weber-7 Heartland Office 91
7	the time of trial.)		Visit 3/17/09
8		7	HAMMONSP_HEOGB_MDR00002-5
9		8	Weber-8 Daviess Community 102
10			Hospital, History
11		9	& Physical
12			5/5/09
13		10	HAMMONSP_DAVCH_MDR00015-16
14		11	Weber-9 Start Coping 112
15			Start Living
16		12	Slide Deck
17			ETH.MESH.03906037-52
18		13	
19			Weber-10 FDA Public Health 117
20		14	Notification
21			10/20/08
22		15	
23			Weber-11 Dyspareunia and Mesh 118
24		16	Erosion After Vaginal
		17	Mesh Replacement with a
			Kit Procedure
		18	(Boyles)
			Weber-12 Does the Prolift 120
		19	System Cause Dyspareunia?
			(Lowman)
		20	
			Weber-13 ACOG Practice 121
		21	Bulletin Pelvic Organ
			Prolapse
		22	Obstetrics & Gynecology
		23	
		24	

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<p style="text-align: right;">Page 6</p> <p>1 - - -</p> <p>2 EXHIBITS (Cont'd.)</p> <p>3 - - -</p> <p>4</p> <p>5 NO. DESCRIPTION PAGE</p> <p>6 Weber-14 Deaconess Women's 147</p> <p> Hospital</p> <p>7 Operative Note</p> <p> 12/15/09</p> <p>8 HAMMONSP_WHC_MDR00006</p> <p>9 Weber-15 Operative/Procedure 148</p> <p> Report (Heit)</p> <p>10 11/28/12</p> <p> HAMMONSP_RFC_MDR00088-91</p> <p>11</p> <p>12 Weber-16 Operative/Procedure 148</p> <p> Report (Heit)</p> <p> HAMMONSP_RFC_MDR00086-87</p> <p>13</p> <p>14 - - -</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 8</p> <p>1 - - -</p> <p>2 ... ANNE M. WEBER, M.D.,</p> <p>3 having been first duly sworn, was</p> <p>4 examined and testified as follows:</p> <p>5 - - -</p> <p>6 EXAMINATION</p> <p>7 - - -</p> <p>8 BY MR. MORIARTY:</p> <p>9 Q. Tell us your full name,</p> <p>10 please.</p> <p>11 A. Anne Margaret Weber.</p> <p>12 Q. Okay. You are Dr. Weber?</p> <p>13 A. Yes.</p> <p>14 Q. I know you've been through</p> <p>15 depositions, and I know you've testified</p> <p>16 in court. Just to remind you, if you do</p> <p>17 not understand my question, please just</p> <p>18 tell me and I'll make it clear to you.</p> <p>19 Okay?</p> <p>20 A. Yes.</p> <p>21 Q. All right. How old are you,</p> <p>22 Dr. Weber?</p> <p>23 A. 53.</p> <p>24 (Document marked for</p>
<p style="text-align: right;">Page 7</p> <p>1 - - -</p> <p>2 DEPOSITION SUPPORT INDEX</p> <p>3 - - -</p> <p>4</p> <p>5 Direction to Witness Not to Answer</p> <p>6 PAGE LINE</p> <p> 117 24</p> <p>7 118 19</p> <p> 213 16</p> <p>8</p> <p>9 Request for Production of Documents</p> <p>10 PAGE LINE</p> <p> None.</p> <p>11</p> <p>12 Stipulations</p> <p>13 PAGE LINE</p> <p> None.</p> <p>14</p> <p>15 Questions Marked</p> <p>16 PAGE LINE</p> <p> None.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 9</p> <p>1 identification as Exhibit</p> <p>2 Weber-1.)</p> <p>3 BY MR. MORIARTY:</p> <p>4 Q. I'm going to hand you what</p> <p>5 I've marked as Exhibit 1. I apologize</p> <p>6 for the thickness. These were printed</p> <p>7 just on one side.</p> <p>8 Is that your report in this,</p> <p>9 the Hammons case, plus the CV that you</p> <p>10 attached to it and the reliance list?</p> <p>11 MR. MORIARTY: Off the</p> <p>12 record.</p> <p>13 (Whereupon, a discussion was</p> <p>14 held off the record.)</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. MORIARTY:</p> <p>17 Q. So that is your report in</p> <p>18 this case and the reliance list?</p> <p>19 A. Yes.</p> <p>20 Q. All right. The address</p> <p>21 that's at the top, is that your home</p> <p>22 address?</p> <p>23 A. Yes.</p> <p>24 Q. And you have an office</p>

3 (Pages 6 to 9)

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<p style="text-align: right;">Page 10</p> <p>1 within your home?</p> <p>2 A. Yes.</p> <p>3 Q. Do you have any employees?</p> <p>4 A. No.</p> <p>5 Q. Okay. So the research that</p> <p>6 you do and the assembly of this sort of a</p> <p>7 report is something that you do yourself?</p> <p>8 A. Yes.</p> <p>9 Q. All right. Do you have any</p> <p>10 research collaborators or subcontractors</p> <p>11 that you hire to do research on matters</p> <p>12 like this?</p> <p>13 A. No.</p> <p>14 Q. Now, I think, as you</p> <p>15 understand, I'm here to ask you about</p> <p>16 your opinions regarding Pat Hammons.</p> <p>17 I've done my best to eliminate general</p> <p>18 opinion questions that you may have been</p> <p>19 asked before. There may be times that I</p> <p>20 stumble into one, if you'll excuse that.</p> <p>21 Sometimes I need to do it as</p> <p>22 background in context for a certain</p> <p>23 Hammons issue. Do you understand that?</p> <p>24 MR. SLATER: She may</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Okay.</p> <p>2 Q. All right. In 2015, have</p> <p>3 you resumed your license and the practice</p> <p>4 of medicine?</p> <p>5 A. No.</p> <p>6 Q. In 2015, did you take any</p> <p>7 privileges at any hospital?</p> <p>8 A. No.</p> <p>9 Q. In 2015, have you seen or</p> <p>10 examined any patients?</p> <p>11 A. No.</p> <p>12 Q. In 2015, have you looked at</p> <p>13 any pathological specimens under a</p> <p>14 microscope?</p> <p>15 A. No.</p> <p>16 Q. In 2015, have you</p> <p>17 participated in the conduct of any</p> <p>18 clinical trials?</p> <p>19 A. No.</p> <p>20 Q. In 2015, have you spoken at</p> <p>21 any continuing medical education</p> <p>22 conferences?</p> <p>23 A. No.</p> <p>24 Q. Have you spoken at any legal</p>
<p style="text-align: right;">Page 11</p> <p>1 understand, but I'm going to</p> <p>2 object if you go into areas that</p> <p>3 are outside the agreement.</p> <p>4 MR. MORIARTY: I understand</p> <p>5 that.</p> <p>6 MR. SLATER: I'm not going</p> <p>7 to have her answer those</p> <p>8 questions. We have an agreement</p> <p>9 that's a national agreement.</p> <p>10 MR. MORIARTY: I understand.</p> <p>11 I'm just asking if she</p> <p>12 understands.</p> <p>13 MR. SLATER: She's here to</p> <p>14 answer questions. I'm the lawyer.</p> <p>15 Please continue.</p> <p>16 BY MR. MORIARTY:</p> <p>17 Q. Do you understand what I'm</p> <p>18 saying?</p> <p>19 A. Yes.</p> <p>20 Q. Okay.</p> <p>21 Now, I want to find out some</p> <p>22 things about your background that may be</p> <p>23 new or may not be new from just this</p> <p>24 calendar year. Okay?</p>	<p style="text-align: right;">Page 13</p> <p>1 conferences in 2015?</p> <p>2 A. No.</p> <p>3 Q. In 2015, have you either</p> <p>4 published or submitted to be published</p> <p>5 any articles in the peer-reviewed medical</p> <p>6 literature?</p> <p>7 A. No.</p> <p>8 Q. In 2015, have you been hired</p> <p>9 to consult with any drug or device</p> <p>10 manufacturer?</p> <p>11 A. No.</p> <p>12 Q. Was there any literature</p> <p>13 published in 2015 on which you are</p> <p>14 relying for opinions in this case?</p> <p>15 MR. SLATER: Objection. Do</p> <p>16 you want her to go through her</p> <p>17 reliance list and see if there's</p> <p>18 any 2015 articles on it? I mean,</p> <p>19 whatever is on her reliance list</p> <p>20 is what she's relying on.</p> <p>21 BY MR. MORIARTY:</p> <p>22 Q. Doctor, is the reliance</p> <p>23 list, the medical literature portion, in</p> <p>24 chronological order by year?</p>

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<p style="text-align: right;">Page 14</p> <p>1 A. No.</p> <p>2 Q. Would you -- do you know off</p> <p>3 the top of your head whether there are</p> <p>4 any 2015 articles that you've added to</p> <p>5 the reliance list?</p> <p>6 A. I don't know that off the</p> <p>7 top of my head.</p> <p>8 Q. Okay. Would you like to</p> <p>9 check and look?</p> <p>10 MR. SLATER: You want her to</p> <p>11 go through a 40-page reliance</p> <p>12 list?</p> <p>13 MR. MORIARTY: Well, it's</p> <p>14 your list.</p> <p>15 MR. SLATER: What does it</p> <p>16 matter? I mean, please. This</p> <p>17 isn't -- she's here -- you're here</p> <p>18 to ask specific opinions about</p> <p>19 Ms. Hammons. So what literature</p> <p>20 she's looked at -- literature</p> <p>21 she's looked at, actually isn't</p> <p>22 what you should be asking about</p> <p>23 today. You should be asking about</p> <p>24 Patricia Hammons, sir.</p>	<p style="text-align: right;">Page 16</p> <p>1 reliance list. You can read the</p> <p>2 dates on the articles just as well</p> <p>3 as she can. I'm not really sure</p> <p>4 of the point of this.</p> <p>5 I would anticipate that</p> <p>6 we'll be done before 4 o'clock.</p> <p>7 Right?</p> <p>8 MR. MORIARTY: I don't know.</p> <p>9 MR. SLATER: I would expect</p> <p>10 to be. Dr. Weber has a train back</p> <p>11 to Maryland, and I have meetings.</p> <p>12 Let the record reflect, Dr.</p> <p>13 Weber is continuing to flip page</p> <p>14 by page trying to answer defense</p> <p>15 counsel's questions about whether</p> <p>16 or not any of the articles on the</p> <p>17 reliance list that he's had in his</p> <p>18 hands for however long it's been</p> <p>19 -- weeks or months, I don't even</p> <p>20 know when it was served -- whether</p> <p>21 or not it says 2015 on any of the</p> <p>22 articles, even though he obviously</p> <p>23 could read that for himself.</p> <p>24 And for the record, at the</p>
<p style="text-align: right;">Page 15</p> <p>1 BY MR. MORIARTY:</p> <p>2 Q. Okay. Would you like to</p> <p>3 look at your list and tell me if there</p> <p>4 are any new 2015 articles on which you</p> <p>5 are relying for your opinions?</p> <p>6 A. If you like.</p> <p>7 MR. SLATER: Go ahead and</p> <p>8 take as long as you want,</p> <p>9 Dr. Weber. I guess you have to go</p> <p>10 through every page and see if the</p> <p>11 articles are published this year,</p> <p>12 even though counsel has it and he</p> <p>13 obviously knows if any are dated</p> <p>14 2015.</p> <p>15 Although I will say,</p> <p>16 Counsel, this deposition is not</p> <p>17 going all night. So if you're</p> <p>18 going to --</p> <p>19 MR. MORIARTY: I don't</p> <p>20 intend to go into the night.</p> <p>21 MR. SLATER: -- this is a</p> <p>22 waste of time.</p> <p>23 With all due respect, this</p> <p>24 is a waste of time. You have the</p>	<p style="text-align: right;">Page 17</p> <p>1 end of the day when we're ready to</p> <p>2 go and we've wasted 20 minutes on</p> <p>3 this, that time is going to come</p> <p>4 out of this deposition. It's not</p> <p>5 going to be that we're going to go</p> <p>6 on all day because Dr. Weber's</p> <p>7 forced to read something that</p> <p>8 counsel could have read himself.</p> <p>9 MR. MORIARTY: I understand.</p> <p>10 We're on the record. It's part of</p> <p>11 the time.</p> <p>12 Let me interrupt for a</p> <p>13 second. Doctor, what page are you</p> <p>14 on?</p> <p>15 MR. SLATER: She'll keep</p> <p>16 looking. She won't answer till I</p> <p>17 come back in the room.</p> <p>18 BY MR. MORIARTY:</p> <p>19 Q. Doctor, what page are you</p> <p>20 on?</p> <p>21 MR. SLATER: Please don't</p> <p>22 ask a question. I'm outside the</p> <p>23 room.</p> <p>24 (Brief pause.)</p>

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<p style="text-align: right;">Page 18</p> <p>1 MR. MORIARTY: All I did was 2 ask her what page she was on. 3 MR. SLATER: Sorry. If I'm 4 not in the room, I don't want you 5 questioning when I'm not in the 6 room. 7 MR. MORIARTY: Well, you 8 were in the room. 9 MR. SLATER: I was walking 10 out with a phone. I got a very 11 important call, I thought. 12 Now you can answer, Doctor. 13 THE WITNESS: 85. 14 BY MR. MORIARTY: 15 Q. When you get to 101, please 16 let me know. 17 A. Okay. Page 101. 18 Q. Page 101. Is that where it 19 transitions into "Additional Documents"? 20 A. It says that on the page. 21 Q. Okay. From your review of 22 the medical literature section of the 23 reliance list, were there any 2015 24 articles?</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Have you taken any 2 additional courses in any other line of 3 study, be it engineering, biomaterials, 4 anything else? Formal education. 5 A. No. 6 Q. In 2015, have you performed 7 any studies on contraction or shrinkage 8 rates of polypropylene mesh? 9 A. No. 10 Q. In 2015, have you performed 11 or participated in any studies about the 12 degradation of polypropylene mesh? 13 A. No. 14 Q. In 2015, have you 15 participated in any studies on the 16 distinction between laser- or 17 mechanical-cut mesh? 18 A. No. 19 Q. In 2015, have you drafted 20 any labels for medical devices? 21 A. No. 22 Q. In 2015, have you 23 participated in preparing a 510(k) 24 application to the FDA?</p>
<p style="text-align: right;">Page 19</p> <p>1 MR. SLATER: The medical 2 literature didn't end on Page 101, 3 Counsel. It says "Abstracts." It 4 says "Other Documents" -- 5 THE WITNESS: That's what 6 I'm trying to discern. 7 BY MR. MORIARTY: 8 Q. All I want to know is if in 9 the medical literature section there were 10 any 2015 articles. 11 A. No. 12 Q. Okay. 13 MR. SLATER: Do you want her 14 to stop reading that? You want 15 her to go any further? 16 MR. MORIARTY: No. Thank 17 you. 18 MR. SLATER: So you stopped 19 on Page 101. Okay. 20 BY MR. MORIARTY: 21 Q. Doctor, in 2015, have you 22 taught at any medical school or residency 23 program? 24 A. No.</p>	<p style="text-align: right;">Page 21</p> <p>1 A. No. 2 Q. Do you continue to subscribe 3 to medical journals? 4 A. Yes. 5 Q. Which ones do you subscribe 6 to, continuing now? 7 A. The American Journal of 8 Obstetrics & Gynecology. 9 Q. That is "The Gray Journal"? 10 A. Yes. 11 Q. Okay. And that is the only 12 one you continue to subscribe to? 13 A. Yes. 14 Q. In order to subscribe to 15 "The Gray Journal," do you have to be a 16 member of ACOG? 17 A. I don't know. 18 Q. And then I assume if you 19 needed to do medical literature today, 20 for purposes of this case, you could 21 access various resources on the Internet 22 or go to a medical library? 23 A. Yes. 24 Q. Okay. I'm sorry I didn't</p>

6 (Pages 18 to 21)

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<p style="text-align: right;">Page 22</p> <p>1 bring extra copies of this. The location 2 and date of today is highlighted on this 3 document. But this is, Dr. Weber, 4 Exhibit 3. It is the notice for this 5 deposition. 6 MR. SLATER: Counsel, is 7 that the notice that you told me 8 in an e-mail don't worry about it, 9 you only wanted a couple of things 10 from it? Yeah, that is. 11 You realize you wrote me an 12 e-mail -- 13 MR. MORIARTY: Yeah. 14 MR. SLATER: -- that said 15 don't worry about this -- 16 MR. MORIARTY: Mr. Slater, I 17 remember my e-mail. You haven't 18 even heard the question yet. 19 (Document marked for 20 identification as Exhibit 21 Weber-3.) 22 BY MR. MORIARTY: 23 Q. Is that the notice for this 24 deposition?</p>	<p style="text-align: right;">Page 24</p> <p>1 MR. MORIARTY: Okay. 2 MR. SLATER: Would you like 3 copies of those? 4 MR. MORIARTY: Yes, please. 5 MR. SLATER: Say "please" 6 again. Just kidding. 7 These are our invoices dated 8 May 5th, June 3, July 1, August 2, 9 2015. 10 MR. MORIARTY: Do you have 11 any objection to me marking them 12 collectively as Exhibit 4? 13 MR. SLATER: I have no 14 objection to that. That sounds 15 like a splendid idea. 16 (Document marked for 17 identification as Exhibit 18 Weber-4.) 19 BY MR. MORIARTY: 20 Q. Dr. Weber, I've had marked 21 as Exhibit 4, a sequence of four letters 22 from you to Mr. Slater's office. And all 23 it has to do with is the amount of time 24 that you've spent on this case. Okay.</p>
<p style="text-align: right;">Page 23</p> <p>1 A. It appears to be. 2 Q. Okay. Have you ever seen it 3 before? 4 A. Yes. 5 Q. All right. Did you bring 6 any documents at all to today's 7 deposition? 8 A. I don't have any hardcopy 9 documents, no. 10 Q. Okay. 11 MR. SLATER: We have -- we 12 have what you asked for. 13 BY MR. MORIARTY: 14 Q. May I have that back, 15 please. 16 MR. MORIARTY: Can I have -- 17 what do you -- I don't know what 18 you have that I asked for. I 19 don't need you to hand me medical 20 records, but if you've got billing 21 entries or anything like that. 22 MR. SLATER: I have -- I 23 have copies of the letters billing 24 for this case.</p>	<p style="text-align: right;">Page 25</p> <p>1 MR. SLATER: And the amounts 2 billed, right? 3 MR. MORIARTY: And the 4 amounts billed. 5 BY MR. MORIARTY: 6 Q. Is that what those are? 7 A. Yes. 8 Q. All right. Did you do any 9 work on this case before 2015? 10 A. No. 11 Q. Other than reviewing your 12 report, any medical records, or 13 depositions specific to Mrs. Hammons, did 14 you do anything else to prepare for your 15 deposition today? 16 A. Yes. 17 Q. Tell me what you did besides 18 those things. 19 A. We met in a group. 20 Q. Okay. 21 MR. SLATER: That's -- 22 that's all work product and 23 privileged. I assume you're not 24 going to get into what we</p>

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<p style="text-align: right;">Page 26</p> <p>1 discussed. 2 BY MR. MORIARTY: 3 Q. How many -- I just want to 4 know how many people were in the group. 5 A. Four. 6 Q. And was the meeting today or 7 yesterday? 8 A. Yesterday. 9 Q. All right. So you had a 10 meeting presumably with Ms. Hammons' 11 legal team. You reviewed her medical 12 records, or re-reviewed them. You 13 reviewed or re-reviewed some depositions. 14 You did those things, 15 correct? 16 A. Yes. 17 Q. All right. Did you review 18 reports from other experts for 19 Mrs. Hammons such as Dr. Zipper, 20 Dr. Pence, any of those? 21 A. I have reviewed Dr. Zipper's 22 report. 23 Q. Okay. Not -- not that of 24 Peggy Pence?</p>	<p style="text-align: right;">Page 28</p> <p>1 A. Yes. 2 Q. Okay. Now, it's my 3 understanding that "primary report" 4 refers to what I have had marked here as 5 Exhibit 2. 6 (Document marked for 7 identification as Exhibit 8 Weber-2.) 9 BY MR. MORIARTY: 10 Q. Weber Exhibit 2. It is a 11 report that you drafted in 2012. Let me 12 get the specific date. June 15, 2012, 13 addressed to Mr. Slater. 14 A. Yes. 15 Q. Okay. And this is a 16 two-volume document; is that right? 17 MR. SLATER: And, Counsel, 18 for the record, it's over 500 19 pages that you've put on the 20 table. We're not going to go 21 through every page to confirm that 22 you actually -- that you have all 23 the pages. 24 MR. MORIARTY: Well --</p>
<p style="text-align: right;">Page 27</p> <p>1 A. No. 2 Q. Or Dr. Elliott? 3 A. No. 4 Q. Okay. Did you review any 5 expert reports for the defense such as 6 Dr. Lowman or Dr. Drolet? 7 A. Yes. 8 Q. Did you review any other 9 defense expert reports besides those two? 10 A. No. 11 Q. Now, in your report, the one 12 that I have marked as Exhibit 1, you make 13 a reference to, I think you used the word 14 "primary report." Do you remember that? 15 A. No. But I don't have any 16 reason to doubt that. 17 MR. SLATER: Why don't you 18 look at it. He'll show you where 19 it is if you're not sure. 20 BY MR. MORIARTY: 21 Q. First place I can easily 22 find it is Page 3 of your report in the 23 second-to-last line, the last word and 24 the first word of the last line.</p>	<p style="text-align: right;">Page 29</p> <p>1 MR. SLATER: So we're taking 2 your representation that you have 3 provided it by other counsel of 4 Ethicon. I assume you don't want 5 me to go through this thing and 6 confirm all the pages are there. 7 MR. MORIARTY: I don't. I 8 just want to make sure that this 9 is what Dr. Weber is referring to 10 as her primary report. All I did 11 was print it. 12 MR. SLATER: Okay. I'm just 13 telling you. 14 MR. MORIARTY: And it is 15 500-some pages long. 16 MR. SLATER: I'm just saying 17 we're not going through every 18 page. That's all. 19 I don't know why you are 20 shaking your head. I'm just 21 making a record. 22 MR. MORIARTY: That's fine. 23 MR. SLATER: If there's a 24 couple pages missing, I don't want</p>

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<p style="text-align: right;">Page 30</p> <p>1 to be distracted by that. I'm not 2 even sure why we're doing this. 3 You're supposed to be asking about 4 her opinions on the Hammons case. 5 MR. MORIARTY: Because she 6 refers to it. And I want to make 7 sure that that's what she's 8 referring to. 9 BY MR. MORIARTY: 10 Q. That's your primary report? 11 A. Yes. 12 Q. Okay. Thank you. Have you 13 ever done a report like Exhibit 2 for any 14 other -- about any other Ethicon product 15 besides Prolift? 16 A. No. 17 Q. Getting back to Exhibit 4, 18 these billing records, I understand that 19 you may be consulting with Mr. Slater on 20 other cases. Okay. For 2014 -- 21 MR. SLATER: She's not going 22 to answer questions about billing 23 on other matters. 24 MR. MORIARTY: Can you just</p>	<p style="text-align: right;">Page 32</p> <p>1 prepared. 2 BY MR. MORIARTY: 3 Q. For 2014, have you done a 4 tax return? 5 A. Yes. 6 Q. Okay. Other than work done 7 for Mr. Slater's law firm in consulting 8 on pelvic mesh cases, did you have any 9 other earned income on your 2014 tax 10 return? 11 A. No. 12 Q. Other than consulting for 13 Mr. Slater on pelvic mesh cases in 2015, 14 to date, to the best of your knowledge, 15 have you had other earned income? 16 A. No. 17 Q. Okay. I want to talk about 18 some risk factors for Mrs. Hammons. 19 Okay? And your report is over there 20 somewhere. You're more than welcome to 21 consult with it or the medical records if 22 you need to answer my question. Do you 23 understand? 24 A. Yes.</p>
<p style="text-align: right;">Page 31</p> <p>1 object? 2 MR. SLATER: My 3 understanding is it's only about 4 this case. 5 MR. MORIARTY: Can you just 6 object? 7 MR. SLATER: I'm just 8 telling you that we're not going 9 into that. My understanding is -- 10 I thought you knew that. 11 MR. MORIARTY: This will be 12 a lot faster if all you do is 13 object and then instruct her or 14 not instruct her to answer. 15 MR. SLATER: Please 16 continue. 17 MR. MORIARTY: Because I'm 18 going to ask. So just object. 19 MR. SLATER: Why would you 20 ask in violation of agreements? 21 MR. MORIARTY: It's not in 22 violation of the agreement. 23 MR. SLATER: You should talk 24 to other people, then. You're not</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Okay. Do you still 2 subscribe to the view that risk factors 3 for POP fall into the categories of 4 predisposing, inciting, promoting, or 5 decompensating? 6 A. In general, yes. 7 Q. Okay. Did Ms. Hammons have 8 at least two predisposing factors for 9 pelvic organ prolapse, being she was a 10 white female? 11 A. Yes. 12 Q. If a patient like 13 Mrs. Hammons has some of these factors -- 14 and I'll get into the other categories in 15 a minute -- if they are at risk for 16 pelvic organ prolapse in the first place, 17 do the same factors put the patient at 18 risk for recurrence? 19 MR. SLATER: Objection. 20 Ambiguous and multiple other 21 reasons why that question is 22 inappropriate. 23 You can answer it. 24 THE WITNESS: They may.</p>

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<p style="text-align: right;">Page 34</p> <p>1 MR. MORIARTY: Okay.</p> <p>2 MR. SLATER: There's also a</p> <p>3 foundational issue with the</p> <p>4 question too.</p> <p>5 BY MR. MORIARTY:</p> <p>6 Q. They may in what sense, and</p> <p>7 in what sense may they not?</p> <p>8 A. In order to answer that</p> <p>9 question, we would need to go through the</p> <p>10 risk factors one by one.</p> <p>11 Q. Okay. Well, let's go</p> <p>12 through the factors, and then I'll ask</p> <p>13 you that question again. Okay?</p> <p>14 Do we know whether</p> <p>15 Mrs. Hammons had a genetic predisposition</p> <p>16 to pelvic organ prolapse?</p> <p>17 A. I don't think that's known.</p> <p>18 Q. All right. Did Mrs. Hammons</p> <p>19 have at least two inciting risk factors,</p> <p>20 being delivery, vaginal deliveries, and</p> <p>21 surgery, being the hysterectomy?</p> <p>22 A. She had two vaginal</p> <p>23 childbirths. The hysterectomy was not a</p> <p>24 predisposing factor for prolapse.</p>	<p style="text-align: right;">Page 36</p> <p>1 recurrence of prolapse after a repair</p> <p>2 surgery?</p> <p>3 A. They may, yes, in general.</p> <p>4 Q. In what sense may they, and</p> <p>5 in what sense may they not?</p> <p>6 A. If I'm understanding your</p> <p>7 question correctly, you're asking about</p> <p>8 the pathophysiology of recurrent</p> <p>9 prolapse. Is that right?</p> <p>10 Q. Let me bring it specific to</p> <p>11 this case. Was Mrs. Hammons, because of</p> <p>12 these factors, at risk for recurrent</p> <p>13 prolapse after a prolapse repair surgery</p> <p>14 regardless of which technique was chosen?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. What is your</p> <p>17 understanding of for how long</p> <p>18 Mrs. Hammons complained of pelvic organ</p> <p>19 prolapse symptoms prior to when she saw</p> <p>20 Dr. Baker in 2009?</p> <p>21 A. In the records, it's</p> <p>22 recorded as about two years.</p> <p>23 Q. Okay. And what is the first</p> <p>24 medical record that you have seen before</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Because she had it at the</p> <p>2 time of her prolapse surgery?</p> <p>3 A. She had prolapse at the time</p> <p>4 of her prolapse surgery, at which time a</p> <p>5 hysterectomy was done.</p> <p>6 Q. Okay. Did she have at least</p> <p>7 two promoting factors, being obesity and</p> <p>8 smoking?</p> <p>9 MR. SLATER: Objection.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. MORIARTY:</p> <p>13 Q. And did Mrs. Hammons have</p> <p>14 several decompensating risk factors,</p> <p>15 including aging and menopause?</p> <p>16 A. Yes.</p> <p>17 Q. All right. So a couple</p> <p>18 minutes ago I asked you whether -- if a</p> <p>19 woman has these factors, if she's at risk</p> <p>20 for prolapse. And the answer to that is</p> <p>21 correct -- is yes, correct?</p> <p>22 A. In general, yes.</p> <p>23 Q. Do these same predisposing</p> <p>24 factors put the patient at risk for</p>	<p style="text-align: right;">Page 37</p> <p>1 today with a complaint of pelvic organ</p> <p>2 prolapse for Mrs. Hammons?</p> <p>3 A. To answer that accurately, I</p> <p>4 would have to go through the records. I</p> <p>5 don't have that date fixed in my mind.</p> <p>6 Q. Okay. Is the first mention</p> <p>7 of POP in your report a reference to</p> <p>8 Dr. Rohrer, a complaint to Dr. Rohrer in</p> <p>9 2008?</p> <p>10 A. I identify that date. I</p> <p>11 don't -- that date does not mean that she</p> <p>12 hadn't had -- hadn't been diagnosed</p> <p>13 earlier.</p> <p>14 Q. Okay.</p> <p>15 (Document marked for</p> <p>16 identification as Exhibit</p> <p>17 Weber-5.)</p> <p>18 BY MR. MORIARTY:</p> <p>19 Q. Doctor, I've handed you what</p> <p>20 I've had marked as Exhibit 5. It's a</p> <p>21 record that we obtained in the middle of</p> <p>22 August 2015 from Kline & Specter.</p> <p>23 Do you know if you've ever</p> <p>24 seen this document before?</p>

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<p style="text-align: right;">Page 38</p> <p>1 And just so the record is 2 clear, I can tell you what my 3 understanding of this is. An emergency 4 room record, February 1, 2007, from 5 Daviess Community Hospital. 6 A. No, I have not seen this 7 before. 8 Q. Okay. Do you agree with me 9 that it's an emergency room record from 10 Daviess Community Hospital, February 1st 11 of 2007? 12 A. Yes. 13 Q. And the -- on the first 14 page, in the upper left-hand corner, 15 there's a section called "Diagnosis, 16 Symptoms, Procedure." 17 Do you see that? 18 A. I'm sorry. I'm just reading 19 her name, and that's not her name. 20 Q. Okay. Well, if you go down 21 and look at the emergency contact, do you 22 know that Chris Winkler is Patricia 23 Hammons' son? 24 A. I'm aware that he is a</p>	<p style="text-align: right;">Page 40</p> <p>1 please, about a third of the way down, 2 there's a pain assessment. 3 Do you see that? 4 A. Yes. 5 Q. And was she complaining of 6 some vaginal area pain? 7 A. Yes, in the vaginal area. 8 Q. Okay. If a patient has a 9 displaced pessary, can that be painful? 10 A. I'm not sure what you mean 11 by "displaced." 12 Q. Well, somewhere in here I 13 believe it either says that the pessary 14 is displaced or it's crooked or something 15 like that. 16 My question is: Can a 17 displaced pessary, if it's still in place 18 but not aligned where it's supposed to 19 be, can that be painful? 20 A. Yes. 21 Q. Okay. And if you go to the 22 second-to-last page of this, which is the 23 review of systems and history form, do 24 you see where it says "bladder fell"?</p>
<p style="text-align: right;">Page 39</p> <p>1 family member. Yes. 2 Q. Okay. And do you know that 3 Patricia Hammons works at Wal-Mart, which 4 is the listed employer here? 5 A. I see that. 6 Q. Okay. Do you recognize Pat 7 Hammons' birth date being June of 1950 in 8 the upper right? 9 A. No, I don't. I don't. 10 Q. Okay. Let's just assume 11 that this is the same Pat Hammons. So 12 what's the diagnosis, symptoms, procedure 13 there? 14 A. I'm sorry. Where are you 15 again? 16 Q. Upper left under the 17 attending's name. 18 A. Oh, I see. Yes. 19 Q. What does it say? 20 A. C/o, pessary falling out. 21 Q. And do you understand c/o to 22 mean "complains of"? 23 A. Yes. 24 Q. If you go to the third page,</p>	<p style="text-align: right;">Page 41</p> <p>1 A. Yes. 2 Q. All right. So this record 3 would be consistent with a history given 4 to Dr. Baker that her symptoms of pelvic 5 organ prolapse had been in existence for 6 at least two years, correct? He saw her 7 in March of 2009. 8 A. Yes. 9 Q. Okay. And the fact that 10 she's got a pessary as of February 2007 11 is an indication that she's at least had 12 nonsurgical treatment for her cystocele, 13 correct? 14 A. For her prolapse, yes. 15 Q. Okay. Now, from your review 16 of the medical records, did Patricia 17 Hammons give Dr. Rohrer and his staff a 18 history of some stress urinary 19 incontinence in February of 2009? 20 A. To confirm that, I'd need to 21 see the medical records. 22 MR. MORIARTY: Do you have 23 your chart here, Kila? 24 MS. BALDWIN: Which one?</p>

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<p style="text-align: right;">Page 42</p> <p>1 MR. SLATER: I thought you 2 said you had all the records you 3 need. 4 MR. MORIARTY: I do. I'm 5 just asking if you have yours. 6 MR. SLATER: We don't have 7 it here. 8 BY MR. MORIARTY: 9 Q. Doctor, I'm showing you what 10 is a February 19, 2009, Dr. Rohrer office 11 note. And it's my copy, so it's 12 highlighted. 13 Do you see a complaint there 14 for stress urinary incontinence? 15 MR. SLATER: A complaint? 16 BY MR. MORIARTY: 17 Q. A report of a history of 18 stress urinary incontinence? 19 MR. SLATER: Object to the 20 form. The foundation is 21 inaccurate. 22 MR. MORIARTY: Okay. 23 MR. SLATER: It says 24 "diagnoses," Counsel. It doesn't</p>	<p style="text-align: right;">Page 44</p> <p>1 Q. Doctor, did -- do you 2 remember whether Dr. Rohrer did any 3 urodynamic studies in 2009? 4 A. He did not, to my knowledge. 5 Q. Okay. Can I have those 6 records back, please. 7 MR. SLATER: You want her to 8 stop looking. Okay. She stopped 9 looking in response to your 10 request for the records back. 11 MR. MORIARTY: That's fine. 12 BY MR. MORIARTY: 13 Q. Are you going to render 14 opinions in this case that Mrs. Hammons 15 has stress urinary incontinence now that 16 is related to her Prolift procedure in 17 2009? 18 A. I'd have to look at her most 19 recent examination. I can't recall off 20 the top of my head whether she had a 21 stress incontinence complaint when she 22 was evaluated by Dr. Zipper. 23 Q. In your report, did you 24 comment on Dr. Zipper's exam?</p>
<p style="text-align: right;">Page 43</p> <p>1 say complaint, and it doesn't say 2 history. 3 MR. MORIARTY: That's fine. 4 BY MR. MORIARTY: 5 Q. Did Dr. Rohrer diagnose 6 stress urinary incontinence? 7 A. Stress incontinence is 8 listed as a diagnosis, yes. 9 Q. In order for him to diagnose 10 that, would the patient have had to have 11 complained of symptoms consistent with 12 that? 13 A. Not necessarily. 14 Q. Okay. Well, why don't you 15 look at the record and see if there's a 16 physical exam finding where he reproduced 17 stress urinary incontinence or a 18 urodynamic study. 19 You don't remember seeing -- 20 MR. SLATER: Which question 21 do you want her to answer? You're 22 up to three or four questions. 23 I object. It's argumentative. 24 BY MR. MORIARTY:</p>	<p style="text-align: right;">Page 45</p> <p>1 A. Yes. 2 Q. Could you look at that and 3 tell me? 4 A. Yes, I can. 5 In my report on Page 9, 6 second full paragraph, five lines down, I 7 have a sentence that states, "She 8 described worsening frequency and urgency 9 of urination, but no incontinence." 10 Q. And when you say "no 11 incontinence," do you mean no stress 12 incontinence? 13 A. I mean no incontinence. 14 Q. No -- 15 A. Urinary. 16 Q. -- incontinence of any type, 17 be it stress, urge? 18 A. No urinary incontinence, 19 yes. 20 Q. Okay. So you're -- as of 21 today, you're not going to be rendering 22 opinions at trial that Mrs. Hammons has 23 stress urinary incontinence as a result 24 of her Prolift procedure, correct?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A. She does not have stress 2 incontinence symptoms as of Dr. Zipper's 3 report. 4 Q. Okay. So does that mean 5 that you're not going to be rendering 6 opinions at the time of trial about 7 whether she's got stress urinary 8 incontinence as a result of her Prolift 9 procedure? 10 A. I don't think I can answer 11 that question the way you're asking it. 12 She's had interventions 13 since her Prolift surgery. 14 Q. Yes. 15 A. So I just -- I don't think I 16 can answer your question the way it's 17 stated. 18 Q. Okay. So what I'm trying to 19 find out is about her current complaints, 20 not a complaint -- as you know them. 21 Okay. I understand that you haven't seen 22 her and Dr. Zipper hasn't seen her in a 23 month or two. I'm not asking about what 24 complaints she may have made in 2012.</p>	<p style="text-align: right;">Page 48</p> <p>1 it clear in the prelude to my question 2 that I'm not asking you about 2012, what 3 complaints she made then prior to her 4 interventions. I'm asking about now. 5 Okay. 6 A. Okay. So could you rephrase 7 the question again, please. 8 Q. Based on what you know now, 9 you're not going to render opinions at 10 the time of trial that she currently has 11 stress urinary incontinence as a result 12 of her Prolift; is that correct? 13 A. She does not currently have 14 stress urinary incontinence. 15 Q. At all, right? 16 A. She does not currently have 17 stress urinary incontinence. 18 Q. Clarify for me, please, when 19 it is that you stopped practicing 20 medicine. I know it was in 2005 or 2006. 21 But can you tell me specifically when 22 that was? 23 A. I believe that was in 24 May 2006.</p>
<p style="text-align: right;">Page 47</p> <p>1 Okay. I'm asking, to the best of your 2 understanding today, she's not 3 complaining of stress urinary 4 incontinence. Is that true? 5 A. True. 6 Q. All right. So you're not 7 going to be rendering any opinions at the 8 time of trial that she has stress urinary 9 incontinence related to her Prolift 10 procedure? 11 A. I think we've been through 12 this cycle of question and answer. I 13 can't answer that the way you've phrased 14 it. 15 Q. Why can't you answer it? 16 A. Because the fact that she 17 doesn't have stress incontinence symptoms 18 now is not necessarily -- it doesn't 19 exclude the possibility that she has had 20 stress incontinence symptoms in the past 21 that would have been related to the 22 Prolift procedure, because she's had 23 interventions in the intervening time. 24 Q. All right. I thought I made</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Prior to May of 2006, was 2 there a period of time when you were not 3 practicing but had not retired or 4 resigned your license? 5 A. No. 6 Q. Okay. So you were 7 practicing up until May of 2006, correct? 8 A. Yes. 9 Q. Okay. Is that also when you 10 stopped performing surgery? 11 A. No. 12 Q. When did you stop performing 13 surgery? 14 A. In the fall of 2004. 15 Q. Now, obviously Dr. Baker 16 performed a vaginal hysterectomy in May 17 of 2009. You are aware of that? 18 A. Yes. 19 Q. When you were a practicing 20 surgeon, did you perform hysterectomies? 21 A. Yes. 22 Q. Did you perform vaginal and 23 abdominal hysterectomies? 24 A. Yes.</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q. Do you know how many you 2 performed? 3 A. No. 4 Q. Probably a lot, right? 5 A. Probably. 6 Q. Okay. Do you have any 7 criticisms of Dr. Baker for performing a 8 hysterectomy in May of 2009 on 9 Mrs. Hammons? I don't want to talk about 10 technique. I just want to talk about the 11 decision to perform a hysterectomy. Was 12 it indicated in 2009? 13 A. Based on Dr. Baker's 14 surgical judgment, it was indicated. 15 Q. Even -- okay. Assuming 16 Dr. Baker performed just a hysterectomy 17 with no pelvic organ prolapse procedure 18 at all in 2009, was Mrs. Hammons at risk 19 for dyspareunia? 20 A. Speaking in general, 21 dyspareunia is a possible risk factor 22 related to hysterectomy. If you're 23 talking specifically about Mrs. Hammons, 24 that's a different situation.</p>	<p style="text-align: right;">Page 52</p> <p>1 patient who has prolapse? Or are you 2 just describing a patient who's having a 3 vaginal hysterectomy? 4 Q. Just a patient who's having 5 a vaginal hysterectomy. 6 A. So, in general, a general 7 risk for a hysterectomy is dyspareunia. 8 Q. All right. And from your 9 experience and your review of the 10 literature, what was the de novo 11 dyspareunia rate following vaginal 12 hysterectomy, either now or in 2009? 13 A. That's a number that's very 14 hard to pin down because of the different 15 definitions that are used, and many women 16 have concomitant operations, so it's very 17 difficult to parse what may be due 18 strictly to the hysterectomy. 19 So it's very hard to put an 20 absolute number on that rate. 21 Q. How about a range? 22 MR. SLATER: Objection. 23 THE WITNESS: A range has 24 the same problem.</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Okay. Tell me why 2 Mrs. Hammons is a different situation. 3 A. Because the patient you're 4 describing is not Mrs. Hammons. 5 Mrs. Hammons did not just have a 6 hysterectomy, if I understood your 7 question correctly. 8 Q. Okay. Well, you understand 9 my question is a hypothetical? 10 MR. SLATER: I don't 11 understand. 12 THE WITNESS: Well, it's 13 either hypothetical or 14 Mrs. Hammons. It can't be both. 15 BY MR. MORIARTY: 16 Q. Okay. Assume a patient like 17 Mrs. Hammons just had a vaginal 18 hysterectomy in May of 2009. She would 19 have been at some risk for dyspareunia, 20 correct? 21 A. I would just like to 22 clarify. In naming this hypothetical 23 patient as like or describing them as 24 like Mrs. Hammons, are you describing a</p>	<p style="text-align: right;">Page 53</p> <p>1 BY MR. MORIARTY: 2 Q. Okay. Do you know the high 3 end of the range? 4 MR. SLATER: Objection. 5 THE WITNESS: That's the 6 same question. If you ask me for 7 a range, and I replied that has 8 the same problems, then the high 9 end of the range has the same 10 problem also. 11 BY MR. MORIARTY: 12 Q. Okay. My question is just 13 from your own personal experience as a 14 surgeon who used to perform 15 hysterectomies and from your review of 16 the literature. What is your 17 understanding of either the average or 18 the range of the de novo dyspareunia 19 rate? 20 A. I have not done a specific 21 literature review -- 22 MR. SLATER: Objection to 23 the question. 24 THE WITNESS: -- to be able</p>

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<p style="text-align: right;">Page 54</p> <p>1 to answer your question. 2 In my personal surgical 3 experience, I don't recall a 4 patient who had dyspareunia after 5 a hysterectomy alone. 6 BY MR. MORIARTY: 7 Q. Okay. Now, if a patient who 8 has a vaginal hysterectomy is going to 9 develop dyspareunia, is one of the 10 potential factors shortening of the 11 vagina as a result of the trimming that 12 is done as part of the surgery? 13 MR. SLATER: Objection. 14 THE WITNESS: Trimming is 15 not typically done at the time of 16 hysterectomy. 17 BY MR. MORIARTY: 18 Q. Okay. Is foreshortened 19 vagina following hysterectomy a potential 20 cause for dyspareunia? 21 MR. SLATER: Objection. 22 THE WITNESS: In general, 23 yes. 24 BY MR. MORIARTY:</p>	<p style="text-align: right;">Page 56</p> <p>1 breakdown. 2 BY MR. MORIARTY: 3 Q. Okay. Can it be chronic? 4 A. From hysterectomy alone? 5 Q. Yes. 6 A. In general? 7 Q. Yes. 8 A. Uncommonly so, yes. 9 Q. Okay. Let's talk about the 10 options that Dr. Baker had to address 11 Mrs. Hammons' pelvic organ prolapse in 12 May of 2009. Okay? 13 A. Okay. 14 Q. Now, I assume that he could 15 have taken a watchful waiting perspective 16 and not treated her at all, correct? 17 MR. SLATER: Objection to 18 the form. 19 THE WITNESS: That's 20 possible. 21 BY MR. MORIARTY: 22 Q. Okay. If he had chosen that 23 course, what was the likely natural 24 course of her pelvic organ prolapse?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. Okay. Is it true that prior 2 to the procedures Dr. Baker performed in 3 2009, neither he nor Dr. Rohrer nor, to 4 the best of our knowledge, anyone else 5 measured the length of her vagina? 6 A. That's correct. 7 Q. Is the cervix typically 3 to 8 4 centimeters in diameter? 9 A. I don't have a reason to 10 dispute that specific figure. Cervical 11 size varies depending on a whole host of 12 factors. 13 Q. Okay. Now, when I asked you 14 a couple of minutes ago about whether 15 dyspareunia was a potential complication 16 of a vaginal hysterectomy, to your 17 knowledge from the published literature, 18 is there a breakdown of whether that 19 dyspareunia is chronic or transient? 20 MR. SLATER: Objection to 21 the form of the question. 22 You can answer. 23 THE WITNESS: To my 24 knowledge, no, there is no</p>	<p style="text-align: right;">Page 57</p> <p>1 MR. SLATER: Objection to 2 the form. 3 You can answer. 4 THE WITNESS: Yeah, that 5 varies very widely. In some 6 women, the prolapse can be stable 7 for many, many years. In other 8 women, it's a slowly progressive 9 condition, such that it may get 10 worse slowly over time. 11 BY MR. MORIARTY: 12 Q. Okay. Based on your 13 knowledge of what you know about 14 Mrs. Hammons in 2009, 2010, do you have 15 an opinion on what the likely course of 16 her pelvic organ prolapse would have been 17 had Dr. Baker not operated? 18 A. Yeah, I don't have any 19 information on which to respond to that 20 since he -- his was the first-time visit, 21 so I don't have any information in the 22 past to know when she got to the point 23 she was when she saw him in order to 24 speculate about her future course.</p>

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<p style="text-align: right;">Page 58</p> <p>1 Q. Okay. So let me make sure I 2 understand what you just said. 3 If all we have in points of 4 time are this February of 2007 emergency 5 room record and then whatever Dr. Rohrer 6 noted in 2008 up to 2009, that isn't 7 enough information for you to render an 8 opinion about what I just asked you, 9 natural course? Is that what you're 10 telling me? 11 MR. SLATER: Objection. 12 You can answer. 13 THE WITNESS: To my 14 understanding, there's no -- I 15 didn't look specifically for an 16 assessment of the extent of her 17 prolapse in her emergency room 18 record. 19 My understanding from 20 Dr. Rohrer's records was that he 21 did not perform an examination 22 that would identify the level or 23 degree of prolapse that she had. 24 So even though she was</p>	<p style="text-align: right;">Page 60</p> <p>1 emergency room record. I just -- I know 2 the things that you pointed out to me. 3 Do you want me to read this 4 emergency room record to be able to 5 answer that question? 6 Q. No. All we know is that she 7 had one in February of 2007 and 8 apparently wasn't using one when she 9 reported to Dr. Rohrer in 2008 or to 10 Dr. Baker in 2009. Okay. Just those 11 facts. 12 Is it unlikely that she 13 would have accepted pessary as a 14 treatment for her pelvic organ prolapse 15 in 2009? 16 MR. SLATER: Objection. You 17 can answer. 18 THE WITNESS: I don't know. 19 That's speculation. 20 BY MR. MORIARTY: 21 Q. What other nonsurgical 22 treatments would have been likely to have 23 been available, acceptable options for 24 Dr. Baker to offer Mrs. Hammons in May of</p>
<p style="text-align: right;">Page 59</p> <p>1 assessed at those points in time, 2 I don't have any extra information 3 about the level of her prolapse in 4 2007 or 2008 that would help me 5 predict what might happen to her 6 after Dr. Baker sees her in 2009. 7 BY MR. MORIARTY: 8 Q. Okay. Was Mrs. Hammons -- 9 I'm sorry. Let me rephrase that. 10 Would a pessary have been -- 11 would a pessary likely have been a 12 successful treatment for her in 2009? 13 A. Successful pessary use also 14 depends on a variety of factors, one of 15 them being the level of prolapse and -- 16 well, I'll stop there. 17 Q. Given what you know about 18 what happened to Mrs. Hammons in February 19 of 2007 and the fact that thereafter at 20 some point she discontinued using her 21 pessary, is it likely that she would not 22 have accepted pessary as a treatment 23 option in 2009? 24 A. Now, I haven't read this</p>	<p style="text-align: right;">Page 61</p> <p>1 2009? 2 A. In addition to the pessary, 3 you mean? 4 Q. Yep. 5 A. It depends on her symptoms. 6 Q. Do you have enough 7 information about her symptoms from 8 Dr. Baker's medical records to answer 9 that question? 10 A. No. The doctor interviewing 11 the patient and examining the patient 12 always has more information than what's 13 recorded in the medical record. So, no, 14 I don't have that information that he 15 had. 16 Q. Okay. Let me get back to a 17 pessary for a second. Assuming that 18 Dr. Baker truly found a Grade 4 cystocele 19 and Mrs. Hammons had already tried and 20 stopped using a pessary before, is it 21 unlikely that the pessary was a viable 22 option for her in 2009? 23 MR. SLATER: Objection. You 24 can answer.</p>

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<p style="text-align: right;">Page 62</p> <p>1 THE WITNESS: I'm sorry. 2 Could you repeat the last part of 3 the sentence? 4 BY MR. MORIARTY: 5 Q. Is it unlikely that a 6 pessary was a viable option for her in 7 2009? 8 A. No. It was not unlikely. 9 Q. Was it unlikely to be 10 accepted as an option in 2009? 11 MR. SLATER: Objection to 12 the form of the question. 13 THE WITNESS: I don't know. 14 The interaction between the doctor 15 and the patient and her symptoms 16 and her goals drive treatment 17 decisions. And I don't have that 18 information. 19 BY MR. MORIARTY: 20 Q. Okay. If she had a Grade 4 21 cystocele as Dr. Baker writes in his 22 notes, and she had already tried and 23 stopped using a pessary and she wanted to 24 remain sexually active, is it unlikely</p>	<p style="text-align: right;">Page 64</p> <p>1 they typically would accept it, knowing 2 what you know about pessaries. 3 A. It really depends on her 4 goals for treatment. 5 Q. Okay. 6 A. Is now a good time for a 7 break? 8 Q. Sure. If you want one. 9 A. Please. 10 (Short break.) 11 BY MR. MORIARTY: 12 Q. Dr. Weber, was it reasonable 13 for Dr. Baker to operate on Mrs. Hammons 14 for pelvic organ prolapse in 2009? 15 A. Based on the discussion that 16 he had with her, all of which is not 17 recorded in the records, I would make the 18 assumption that, yes, he and she jointly 19 determined that it was reasonable. 20 Q. Okay. So when we talk about 21 his surgical options, if he was going to 22 perform a vaginal hysterectomy, how many 23 surgical options did he have at that 24 point to treat her pelvic organ prolapse?</p>
<p style="text-align: right;">Page 63</p> <p>1 that a pessary would have been an 2 acceptable option to the patient in May 3 of 2009? 4 A. No, it is not unlikely. 5 Q. Okay. 6 A. It is not -- I'm sorry. Now 7 I'm confused by the double negatives. 8 No, I'm -- could you repeat the question. 9 I'm sorry. 10 Q. Let me ask this another way. 11 During your own practice, I 12 assume you had experience counseling 13 patients about pessaries. Is that true? 14 A. Yes. 15 Q. Okay. And in patients who 16 had a Stage IV prolapse of any type and 17 wanted to remain sexually active and had 18 already tried and stopped pessary use 19 once, did your patients tend to accept 20 pessaries on a second try? 21 A. It would certainly be 22 something that I would discuss with them. 23 Q. Okay. I'm sure you would to 24 be thorough. But the question is whether</p>	<p style="text-align: right;">Page 65</p> <p>1 MR. SLATER: Objection. 2 Foundation. 3 THE WITNESS: At least 4 three. 5 BY MR. MORIARTY: 6 Q. Okay. And they were what? 7 A. Well, she had an anterior 8 and uterine prolapse. So her anterior 9 prolapse could be addressed by an 10 anterior vaginal repair, and there are a 11 number of techniques to accomplish that. 12 Addressing her uterine 13 prolapse, techniques that can be 14 performed vaginally include a uterosacral 15 ligament suspension, a sacrospinous 16 ligament fixation, and iliococcygeus 17 repair. 18 Q. All right. So I want to 19 make sure I understand this. And, of 20 course, Prolift was an option at the 21 time, whether you agree with its use or 22 not. It was an option at the time, 23 correct? 24 A. It was an option at the</p>

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<p style="text-align: right;">Page 66</p> <p>1 time.</p> <p>2 Q. Okay. And something like</p> <p>3 Gynemesh PS was also an option at that</p> <p>4 time, transvaginally, correct?</p> <p>5 A. The Gynemesh PS alone could</p> <p>6 have been used to address her anterior</p> <p>7 Prolift -- prolapse. Excuse me.</p> <p>8 Q. Did -- as a surgeon, would</p> <p>9 it make sense to do a vaginal</p> <p>10 hysterectomy but an abdominal</p> <p>11 sacrocolpopexy?</p> <p>12 A. No.</p> <p>13 Q. Okay. So if you were going</p> <p>14 to do an abdominal sacrocolpopexy, you'd</p> <p>15 probably do an abdominal hysterectomy?</p> <p>16 A. If a hysterectomy was part</p> <p>17 of the procedure, yes, it would be done</p> <p>18 abdominally.</p> <p>19 Q. Okay. All right. So if I</p> <p>20 understood you correctly, to address the</p> <p>21 uterine prolapse, there were at least</p> <p>22 three options, and you named them,</p> <p>23 correct?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 68</p> <p>1 decisionmaking process? I mean, I know</p> <p>2 you wrote this in 2012. But at that</p> <p>3 point, you were talking generally?</p> <p>4 A. In general, yes.</p> <p>5 Q. Of the options that you</p> <p>6 mentioned for the uterine prolapse and</p> <p>7 the anterior prolapse, just the native</p> <p>8 tissue repairs, many of those had been in</p> <p>9 use for many years before 2009; is that</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. And of all the options that</p> <p>13 you mentioned to me -- I'm sorry. Let me</p> <p>14 take a step back.</p> <p>15 What are the three native</p> <p>16 tissue repairs that would have been</p> <p>17 available to Dr. Baker? I assume</p> <p>18 anterior colporrhaphy?</p> <p>19 A. Yes.</p> <p>20 Q. What else?</p> <p>21 A. Paravaginal repair and a</p> <p>22 site-specific fascial defect repair.</p> <p>23 Q. Okay. So of the six native</p> <p>24 tissue techniques that you've mentioned,</p>
<p style="text-align: right;">Page 67</p> <p>1 Q. And then to address the</p> <p>2 anterior prolapse, you said that there</p> <p>3 were a number of different vaginal repair</p> <p>4 techniques. Without naming them, how</p> <p>5 many do you think there are?</p> <p>6 A. Three.</p> <p>7 Q. Okay.</p> <p>8 A. Three -- let me amend that.</p> <p>9 Three native tissue repairs.</p> <p>10 Q. Okay. Now, if you go to</p> <p>11 Exhibit 2, which is your -- what's been</p> <p>12 called your primary report, this one.</p> <p>13 A. Yes.</p> <p>14 Q. And you go to Page 8, back</p> <p>15 in 2012, from Pages 8 through 10, you</p> <p>16 talk about the alternatives to the</p> <p>17 Prolift.</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. All right. And would --</p> <p>21 would your opinions about the</p> <p>22 alternatives that were available to</p> <p>23 Dr. Baker in 2009, would this material</p> <p>24 from Exhibit 2 still apply to that</p>	<p style="text-align: right;">Page 69</p> <p>1 how many of those had been the subject of</p> <p>2 evidence-based controlled trials by 2009?</p> <p>3 MR. SLATER: What is the</p> <p>4 question?</p> <p>5 THE WITNESS: Clarify --</p> <p>6 MR. MORIARTY: Could</p> <p>7 you just read it back?</p> <p>8 (Whereupon, the</p> <p>9 court reporter read back the</p> <p>10 requested portion of testimony.)</p> <p>11 BY MR. MORIARTY:</p> <p>12 Q. By 2009.</p> <p>13 A. Can you clarify what you</p> <p>14 mean by evidence-based controlled trials?</p> <p>15 Q. Okay. Let's take out</p> <p>16 evidence-based and just say controlled</p> <p>17 trials reported in the peer-reviewed</p> <p>18 literature.</p> <p>19 A. Can you tell me what you</p> <p>20 mean by controlled trials?</p> <p>21 Q. Well, I think you have,</p> <p>22 like, a subspecialty degree in</p> <p>23 participating in clinical trials, don't</p> <p>24 you? Isn't "controlled trials" a term of</p>

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<p style="text-align: right;">Page 70</p> <p>1 art?</p> <p>2 A. Sir, I'm just trying to</p> <p>3 understand your question so I can answer</p> <p>4 it appropriately. I know what it means</p> <p>5 to me. I'm -- I'm asking what it means</p> <p>6 to you so I can be sure to answer</p> <p>7 responsively.</p> <p>8 Q. I want -- I want you to</p> <p>9 answer as it means to you. As controlled</p> <p>10 trials means to you.</p> <p>11 A. Okay. Were any of the</p> <p>12 procedures -- I'm sorry. Now you're</p> <p>13 going to have to start again with the</p> <p>14 beginning of the question.</p> <p>15 Q. What I'm trying to figure</p> <p>16 out -- and I will try to make this go</p> <p>17 faster.</p> <p>18 I've seen writings in the</p> <p>19 peer-reviewed literature, including</p> <p>20 things you've written that talk about the</p> <p>21 lack of clinical trials on some of these</p> <p>22 procedures, even many of the old ones</p> <p>23 that have been around for years and years</p> <p>24 and years. Okay?</p>	<p style="text-align: right;">Page 72</p> <p>1 include a trial comparing</p> <p>2 colporrhaphy to a use of mesh?</p> <p>3 MR. MORIARTY: Sure. As</p> <p>4 long as it was reported before May</p> <p>5 of 2009.</p> <p>6 THE WITNESS: To the best of</p> <p>7 my remembering at the moment, two.</p> <p>8 BY MR. MORIARTY:</p> <p>9 Q. Okay. And just so we're</p> <p>10 clear for the record, by May of 2009,</p> <p>11 Prolift had been -- the 510(k) had been</p> <p>12 cleared by the FDA, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Do you -- are you</p> <p>15 going to express any opinions about</p> <p>16 whether the best surgical course for</p> <p>17 Mrs. Hammons in May of 2009 was vaginal</p> <p>18 hysterectomy plus a native tissue</p> <p>19 prolapse procedure, or is it your opinion</p> <p>20 that he should have done abdominal</p> <p>21 sacrocolpopexy to address her prolapse?</p> <p>22 A. I'm sorry. Could you repeat</p> <p>23 the question?</p> <p>24 Q. Sure. Just so we don't go</p>
<p style="text-align: right;">Page 71</p> <p>1 A. Okay.</p> <p>2 Q. So what I'm trying --</p> <p>3 MR. SLATER: Objection to</p> <p>4 the characterization.</p> <p>5 BY MR. MORIARTY:</p> <p>6 Q. So what I'm trying to find</p> <p>7 out is, of the options available to</p> <p>8 Dr. Baker, putting aside mesh for right</p> <p>9 now, which one of those had been subject</p> <p>10 to controlled trials?</p> <p>11 Let me take one more step</p> <p>12 back. Let's just address the ones for</p> <p>13 the anterior repair, not even the</p> <p>14 uterine. Okay. Just the three you</p> <p>15 mentioned: anterior colporrhaphy,</p> <p>16 paravaginal repair, and site-specific</p> <p>17 fascial defect repair. How many of those</p> <p>18 have been subjected to controlled trials?</p> <p>19 A. One.</p> <p>20 Q. Which one?</p> <p>21 A. Anterior colporrhaphy.</p> <p>22 Q. How many trials by 2009, to</p> <p>23 the best of your knowledge?</p> <p>24 MR. SLATER: Would that</p>	<p style="text-align: right;">Page 73</p> <p>1 off on a complete tangent talking about</p> <p>2 abdominal sacrocolpopexy. Okay.</p> <p>3 Although it was an option available to</p> <p>4 Dr. Baker in 2009, because of the uterine</p> <p>5 prolapse and assuming he was going to do</p> <p>6 a hysterectomy, is it your opinion that</p> <p>7 the issue in this case and the surgical</p> <p>8 decision we should be talking about in</p> <p>9 this case is whether vaginal hysterectomy</p> <p>10 and a native tissue procedure was the</p> <p>11 appropriate way to go, or should we be</p> <p>12 talking about abdominal hysterectomies</p> <p>13 and abdominal sacrocolpopexies?</p> <p>14 MR. SLATER: Objection to</p> <p>15 the foundation of your question.</p> <p>16 THE WITNESS: Well, from</p> <p>17 what I understand from Dr. Baker's</p> <p>18 deposition testimony, he wasn't --</p> <p>19 didn't feel himself qualified to</p> <p>20 be performing abdominal</p> <p>21 sacrocolpopexy with or without a</p> <p>22 hysterectomy.</p> <p>23 BY MR. MORIARTY:</p> <p>24 Q. Okay.</p>

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<p style="text-align: right;">Page 74</p> <p>1 A. So I'm still trying to 2 understand your question. Does this 3 apply to what Dr. Baker had to offer 4 Mrs. Hammons? 5 Q. Yes. 6 A. Okay. 7 Q. Or do you think he should 8 have referred her immediately somewhere 9 else for treatment? 10 A. It's Dr. Baker's judgment 11 that he was qualified to provide a 12 prolapse repair for her. 13 Q. Okay. And is it your 14 opinion, based on everything you know 15 about his qualifications, that he was 16 qualified to perform a vaginal 17 hysterectomy combined with, say, an 18 anterior colporrhaphy? 19 A. And -- and only those 20 procedures in treatment of her prolapse? 21 Q. I just used it as an 22 example. Was he qualified to do at least 23 that? 24 A. I -- I don't know. Clearly</p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. MORIARTY: 2 Q. Okay. So you don't have 3 enough information to judge his 4 qualifications or his skill as a surgeon. 5 True? 6 A. That's true. 7 Q. Okay. Putting aside issues 8 regarding the use of mesh, did the 9 vaginal approach to treating 10 Mrs. Hammons' pelvic organ prolapse have 11 a benefit over an abdominal approach of 12 fewer wound complications, less 13 postoperative pain, a shorter hospital 14 stay, and less cost? 15 MR. SLATER: Objection. 16 Foundation. 17 THE WITNESS: That's been 18 reported in the literature. As to 19 hospital stay and cost, those -- 20 hospital stay varies so much with 21 individual practice, and cost 22 depends on so many other 23 variables, but it has been 24 reported, yes.</p>
<p style="text-align: right;">Page 75</p> <p>1 he thought so. 2 Q. Okay. Is it your opinion 3 that Dr. Baker was qualified to treat 4 Mrs. Hammons for the problems that she 5 had in March and May of 2009? 6 A. I'm sorry. I'm struggling. 7 Are you trying to -- are you asking me to 8 judge his quality as a surgeon? 9 Q. I'm not asking you to. I'm 10 just asking whether you have an opinion. 11 Are you going to express an opinion in 12 this case that Dr. Baker was not 13 qualified to treat this patient and he 14 should have referred her in the first 15 instance in March or May of 2009? 16 MR. SLATER: Objection. 17 It's not an opinion that's been 18 drawn. 19 Objection. Foundation. 20 THE WITNESS: I don't think 21 I have enough information to judge 22 Dr. Baker's qualifications, if I'm 23 understanding your question 24 correctly.</p>	<p style="text-align: right;">Page 77</p> <p>1 BY MR. MORIARTY: 2 Q. Okay. In 2009, was it still 3 controversial about whether the abdominal 4 or vaginal route was more effective or 5 durable -- 6 MR. SLATER: Objection. 7 BY MR. MORIARTY: 8 Q. -- when compared with the 9 abdominal approach? 10 MR. SLATER: Objection. 11 These questions are all vague, 12 ambiguous, and lack foundation, 13 this entire line. 14 THE WITNESS: Yeah, I'm not 15 clear if you're comparing a 16 vaginal vault suspension procedure 17 with abdominal sacrocolpopexy. 18 Is that -- is that your 19 question? 20 BY MR. MORIARTY: 21 Q. Any of the transvaginal 22 approaches. Again, not mesh. 23 MR. SLATER: Objection. 24 It's overbroad, vague, ambiguous,</p>

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<p style="text-align: right;">Page 78</p> <p>1 lacks foundation, and multiple 2 parts to that. 3 THE WITNESS: I'm sorry. 4 Okay. So any of the vaginal 5 operations for uterine or apical 6 suspension? 7 BY MR. MORIARTY: 8 Q. Okay. Let me -- let me just 9 make sure you understand the context in 10 which I'm asking this. 11 Dr. Baker had several 12 surgical options available to him, 13 correct? 14 A. Yes. 15 Q. Or he could have referred 16 the patient if he didn't feel comfortable 17 doing what he thought was the most 18 appropriate, correct? 19 A. Yes. 20 Q. Okay. So if he was just 21 comparing abdominal approaches with 22 transvaginal approaches, in 2009, was 23 there still controversy about which 24 approach to the surgery was -- had better</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. Either. He's going to 2 repair them both, theoretically, right? 3 A. An anterior colporrhaphy and 4 abdominal sacrocolpopexy are not 5 comparable. They have totally different 6 indications. 7 Q. Okay. If Dr. -- well, let's 8 just deal with the apical. Is the apical 9 prolapse the uterine prolapse? 10 A. Those terms are 11 interchangeably used, yes. 12 Q. And at the time of surgery, 13 would you have expected Dr. Baker to 14 address the apex of the vagina because of 15 the apical prolapse? 16 A. Yes. 17 Q. All right. In other words, 18 when Dr. Baker removed the uterus, that 19 isn't necessarily going to take care of 20 the apical prolapse; is that correct? 21 A. Correct. It does not. 22 (Document marked for 23 identification as Exhibit 24 Weber-6.)</p>
<p style="text-align: right;">Page 79</p> <p>1 efficacy or durability? 2 A. I can't answer that without 3 knowing exactly what procedures you're 4 referring to. 5 Q. Okay. Let's just take 6 anterior colporrhaphy versus an abdominal 7 approach. 8 MR. SLATER: Abdominal 9 approach to what? The question 10 doesn't make any sense as asked, 11 with all due respect. 12 MR. MORIARTY: To repairing 13 her -- 14 MR. SLATER: There's a lack 15 of foundation. 16 BY MR. MORIARTY: 17 Q. To repairing her pelvic 18 organ prolapse. 19 MR. SLATER: Which prolapse 20 are you talking about, sir? 21 MR. MORIARTY: She had two. 22 THE WITNESS: She had two. 23 So which one are you -- 24 BY MR. MORIARTY:</p>	<p style="text-align: right;">Page 81</p> <p>1 BY MR. MORIARTY: 2 Q. I've handed you Exhibit 6. 3 Is this Dr. Baker's May 5, 2009, 4 operative report? 5 A. Yes. 6 Q. Does he describe a repair of 7 the apex or a suspension of the apex? 8 A. No. 9 Q. What are the consequences to 10 the patient, Mrs. Hammons -- I'm sorry. 11 Let me rephrase that. 12 What are the possible 13 complications or consequences to 14 Mrs. Hammons if Dr. Baker did not address 15 the apex in his repair on May 5, 2009? 16 A. She may develop vaginal 17 vault prolapse. 18 Q. Anything else? 19 A. No. 20 Q. In your opinion, based on 21 your review of the medical records, did 22 she develop subsequent vaginal vault 23 prolapse? 24 A. By the time she saw</p>

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<p style="text-align: right;">Page 82</p> <p>1 Dr. Heit, yes.</p> <p>2 Q. Okay. But not by the time</p> <p>3 she saw Dr. Lackey in the fall of 2009?</p> <p>4 A. Can I refer to his notes? I</p> <p>5 know he diagnosed her with a rectocele.</p> <p>6 Q. Yes. You're welcome to</p> <p>7 review his notes or your report regarding</p> <p>8 his notes.</p> <p>9 A. Right. So Dr. Lackey</p> <p>10 described a Grade 2 to 3 rectocele. He</p> <p>11 did not specifically describe anything</p> <p>12 related to the apex.</p> <p>13 Q. Okay. So if Dr. Baker had</p> <p>14 chosen to perform vaginal hysterectomy</p> <p>15 plus anterior colporrhaphy, what was the</p> <p>16 risk of dyspareunia from that combination</p> <p>17 procedure?</p> <p>18 MR. SLATER: Objection.</p> <p>19 Ambiguous, compound, lacks</p> <p>20 foundation.</p> <p>21 THE WITNESS: We discussed</p> <p>22 this earlier, I think, as to</p> <p>23 what's reported in the literature</p> <p>24 as far as being able to pin that</p>	<p style="text-align: right;">Page 84</p> <p>1 higher, but to give you a number, to say</p> <p>2 X versus Y, the literature just does not</p> <p>3 support that.</p> <p>4 Q. Can you quantify how much</p> <p>5 higher the risk is with Prolift than it</p> <p>6 is with any of the other -- any of the</p> <p>7 three native tissue procedures that we</p> <p>8 were talking about?</p> <p>9 A. Well, the distinction not</p> <p>10 only applies to the number, but to the</p> <p>11 nature of the condition, such that when a</p> <p>12 woman experiences dyspareunia after a</p> <p>13 native tissue repair, it's treatable, the</p> <p>14 scar softens, it sometimes goes away by</p> <p>15 itself, versus the dyspareunia that</p> <p>16 occurs after Prolift, which is related to</p> <p>17 factors like mesh contraction, vaginal</p> <p>18 anatomic distortion, that Ethicon has all</p> <p>19 over their documents that are difficult,</p> <p>20 if not impossible, to treat.</p> <p>21 So you have two totally</p> <p>22 different mechanisms of dyspareunia</p> <p>23 affecting native tissue repairs versus</p> <p>24 Prolift mesh.</p>
<p style="text-align: right;">Page 83</p> <p>1 down to a number. And for all the</p> <p>2 same reasons that I described</p> <p>3 before, it's not possible.</p> <p>4 BY MR. MORIARTY:</p> <p>5 Q. Okay. What about -- is it</p> <p>6 any more possible to pin that down with</p> <p>7 vaginal hysterectomy plus paravaginal</p> <p>8 repair?</p> <p>9 A. No, not to a single number.</p> <p>10 Q. What about a range?</p> <p>11 A. No. Again, we talked about</p> <p>12 ranges. I think we've been through this.</p> <p>13 The same problems exist.</p> <p>14 Q. Okay. Would your answer be</p> <p>15 the same for vaginal hysterectomy plus</p> <p>16 site-specific fascial defect repair?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Do you have an</p> <p>19 opinion as to the risk of dyspareunia</p> <p>20 with a combination of vaginal</p> <p>21 hysterectomy plus Prolift?</p> <p>22 A. And for all the same</p> <p>23 reasons, a specific number can't be</p> <p>24 applied to that. I believe the risk is</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. Okay. And I understand</p> <p>2 that's your opinion. But what I want to</p> <p>3 stick with right now is the specific</p> <p>4 question of whether you can quantify how</p> <p>5 much higher the risk is with vaginal</p> <p>6 hysterectomy plus Prolift as opposed to</p> <p>7 vaginal hysterectomy plus ACPVR or SSFDR.</p> <p>8 MR. SLATER: Objection to</p> <p>9 the form.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: Well,</p> <p>12 dyspareunia that leads to</p> <p>13 apareunia, being completely unable</p> <p>14 to have intercourse, with native</p> <p>15 tissue repair is zero. And with</p> <p>16 Prolift, apareunia occurs. In my</p> <p>17 entire clinical practice,</p> <p>18 everything that I've read about</p> <p>19 sexual function after prolapse</p> <p>20 repairs, the circumstance where a</p> <p>21 woman can never have normal</p> <p>22 functional sex in her entire life</p> <p>23 simply does not occur after native</p> <p>24 tissue repair.</p>

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<p style="text-align: right;">Page 86</p> <p>1 And after Prolift, it does 2 occur. And that's exactly what 3 happened to Mrs. Hammons. 4 BY MR. MORIARTY: 5 Q. And do you know the rate at 6 which apareunia occurs with Prolift? 7 A. No. If Ethicon had studied 8 this before they put it on the market, I 9 may be able to answer your question, or 10 they would become so horrified by the 11 numbers they would decide not to put it 12 on the market altogether, which would be 13 my opinion. 14 Q. Okay. I'm just trying to 15 ask about rates. Okay. So with the 16 three native tissue repairs, you say 17 apareunia never happened in your 18 experience. Is it reported in the 19 literature? 20 A. I've never seen it. 21 Q. Okay. But you say it does 22 happen with vaginal hysterectomy plus 23 Prolift, but you don't know the rate at 24 which it happens, correct?</p>	<p style="text-align: right;">Page 88</p> <p>1 A. Yes. 2 Q. Okay. In 2009, when 3 Dr. Lackey operated on Mrs. Hammons, was 4 dyspareunia a risk of the native tissue 5 posterior repair that he performed? 6 MR. SLATER: Objection. 7 THE WITNESS: In general, 8 the type of repair he performed is 9 a risk for dyspareunia. 10 BY MR. MORIARTY: 11 Q. Okay. Do you know or do you 12 have an opinion about what the -- the 13 rate of dyspareunia is following that 14 type of posterior repair? 15 A. No. Again, the same 16 problems we've been talking about. 17 Q. Now, I want to be clear on 18 this rate of dyspareunia issue. There 19 are rates published in the literature, 20 correct? 21 A. Yes. 22 Q. Okay. So you or I could 23 read a bunch of medical literature and 24 probably lay out 50 studies on this table</p>
<p style="text-align: right;">Page 87</p> <p>1 A. That's correct. 2 Q. Okay. Going back, 3 originally, can you quantify for me, 4 based on your experience or the published 5 literature, how much higher the 6 dyspareunia rate is with Prolift than it 7 is with the three native tissue repairs 8 that were available to Dr. Baker in 2009? 9 A. No. 10 Q. Getting back to abdominal 11 sacrocolpopexy for one second, you're 12 familiar with the CARE study? C-A-R-E. 13 A. Yes. 14 Q. Okay. Would that be a 15 reliable source of information for the -- 16 the erosion or dyspareunia rates 17 following abdominal sacrocolpopexy? 18 A. Yes. Subject to the -- just 19 the limitations of the study population, 20 but yes. 21 Q. Okay. And those 22 limitations, I assume, would be discussed 23 in one or more of the papers reporting 24 the CARE study?</p>	<p style="text-align: right;">Page 89</p> <p>1 that talk about the rates from various 2 studies, correct? 3 A. Yes. 4 Q. Okay. In 2009, was there a 5 surgical approach to pelvic organ 6 prolapse available to Dr. Baker or 7 available on referral to someone else 8 using synthetic mesh that was a safe and 9 effective alternative to Prolift? 10 Did you understand that 11 question? 12 A. No. 13 Q. It wasn't very good. Okay. 14 While we're talking about 15 options to Dr. Baker, some he could have 16 performed, some maybe he would have 17 needed to refer to another physician, 18 whether it was Dr. Lackey or one of 19 Lackey's partners or his own partner or 20 Dr. Heit. Okay. 21 I'm trying to find out is 22 whether in 2009 there was a surgical 23 approach to her pelvic organ prolapse 24 which would involve the use of synthetic</p>

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<p style="text-align: right;">Page 90</p> <p>1 mesh that was a safe alternative in your 2 opinion. 3 A. Alternative to what? 4 Q. Prolift. 5 A. Yes. 6 Q. And that would be what? 7 A. An abdominal sacrocolpopexy. 8 Q. Okay. And to do that 9 procedure involving mesh, you're using 10 something like Gynemesh PS -- 11 MR. SLATER: Objection. 12 BY MR. MORIARTY: 13 Q. -- or similar? In other 14 words, a sheet of mesh, not a mesh kit, 15 correct? 16 A. Correct. 17 Q. And when you were operating 18 as a surgeon, did you do abdominal 19 sacrocolpopexies? 20 A. Yes. 21 Q. Did you use mesh in any of 22 those procedures? 23 A. Yes. 24 Q. Okay. In the beginning of</p>	<p style="text-align: right;">Page 92</p> <p>1 Q. And on the -- let's go to 2 the last two pages. Under the female 3 exam, he has Grade 4 cystocele. Do you 4 see that? 5 A. Yes. 6 Q. And then cervix, it just 7 says prolapse without the S -- or without 8 the E -- I'm sorry -- correct? 9 A. Yes. 10 Q. Now, granted, he does not 11 have a POP-Q score in here, but do you 12 have any reason to disagree that she had 13 a Grade 4 cystocele at the time of this 14 exam? 15 A. Yes. 16 Q. And what -- what, in your 17 opinion, was her degree of cystocele as 18 of March of 2009? 19 A. Based on her deposition 20 testimony, I would say possibly Stage II 21 or early Stage III, using the POP-Q 22 system. 23 Q. And is the basis for that 24 opinion solely Mrs. Hammons' deposition?</p>
<p style="text-align: right;">Page 91</p> <p>1 the CARE study, were you one of the 2 operating surgeons, or were you a 3 consultant to the design of the trial? 4 A. I was the program director 5 of the Pelvic Floor Disorders Network. I 6 was not an investigator providing care at 7 any of the sites. 8 Q. Okay. By 2009, when 9 Dr. Baker operated on Mrs. Hammons, was 10 erosion a known risk of the use of pelvic 11 mesh? 12 A. Yes. 13 (Document marked for 14 identification as Exhibit 15 Weber-7.) 16 BY MR. MORIARTY: 17 Q. Dr. Weber, this is 18 Dr. Baker's March 17, 2009, office note, 19 correct? 20 A. Yes. 21 Q. And you've seen this before 22 as part of your analysis of the facts of 23 this case? 24 A. Yes.</p>	<p style="text-align: right;">Page 93</p> <p>1 A. Yes. 2 Q. Okay. And whether it was a 3 Grade 4 or a Grade 2 to 3, does that make 4 any difference in your opinion for 5 purposes of this case? 6 A. Yes. 7 Q. Okay. Tell me how that 8 makes a difference to your opinion. 9 A. Well, the severity of 10 prolapse always is an important factor in 11 determining -- in helping to determine 12 treatment options as well as 13 understanding patient symptoms. 14 Q. Okay. So are you -- is it 15 your opinion that the treatment would 16 have been different or the outcome would 17 have been different had he scored this 18 appropriately? 19 A. Yes. 20 Q. And what's the difference? 21 A. I think in the interaction 22 between the doctor and the patient, 23 making a decision about treatment and 24 what's expected in terms of outcomes</p>

24 (Pages 90 to 93)

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<p style="text-align: right;">Page 94</p> <p>1 would be different if you're dealing with 2 someone at a relatively low stage of 3 prolapse versus someone who is truly a 4 Stage IV with vaginal eversion. 5 Q. Okay. Are you -- is it your 6 opinion that, had he properly scored 7 this, he would have treated her 8 differently or she would have had a 9 different outcome? 10 A. It's possible, yes. Early 11 stage -- she has relatively early 12 prolapse. 13 Q. Okay. Do you have an 14 opinion, to a reasonable degree of 15 medical probability, as to how the 16 outcome would have been different in this 17 case had he scored this as a 2 to 3 18 cystocele? 19 A. Well, if he had been trained 20 appropriately by Ethicon in their own 21 marketing and -- marketing of the Prolift 22 device, that it was intended to be used 23 for women with advanced prolapse, and if 24 he in his mind decided that his version</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. I'm just trying to 2 understand this sequence that follows 3 from him not scoring her prolapse 4 appropriately. Okay. I want to know the 5 endgame of what happens after he scores 6 her improperly. Okay. 7 Are you saying that had he 8 scored her properly, more likely than 9 not, he would have chosen an anterior 10 colporrhaphy, for example? 11 A. I can't say what -- his 12 decisionmaking regarding the treatment 13 options based on his understanding of 14 what stage of prolapse she had. That's 15 speculation. 16 Q. Okay. Are you saying, to a 17 probability, that had he properly scored 18 her as a two to three, he is likely to 19 have used Prolift? 20 A. I can't answer for his 21 medical judgment in deciding at what 22 level in his mind Prolift was indicated. 23 Q. Okay. So I'm trying to 24 figure out what your opinion is, to a</p>
<p style="text-align: right;">Page 95</p> <p>1 of Grade 4 cystocele meant advanced 2 prolapse, then he would choose Prolift as 3 an option that would be appropriate for 4 her as opposed to what Ethicon itself was 5 saying, was that early stage prolapse was 6 not an appropriate -- patients with early 7 stage prolapse were not appropriate 8 candidates for Prolift. 9 Q. Are you done with your 10 answer? I just want to make sure I 11 understand your answer before I ask my 12 next question. 13 A. Yes. 14 Q. So if I understand you 15 correctly, more likely than not, she was 16 a Grade 2 to 3 as opposed to a Grade 4, 17 and had he properly scored her and 18 properly, in your opinion, operated on a 19 2 to 3, with whatever procedures applied 20 to a 2 to 3, other than a Prolift, her 21 outcome would have been different, 22 correct? 23 A. I'm sorry. That was very 24 long. Can you rephrase, please?</p>	<p style="text-align: right;">Page 97</p> <p>1 probability, what the difference in 2 outcome is because of this scoring 3 discrepancy or scoring error. 4 MR. SLATER: Objection to 5 the foundation for that. 6 THE WITNESS: I'm not saying 7 it's an error. You see, I can't 8 get into Dr. Baker's mind. He 9 recorded a Grade 4. That's what 10 he saw and recorded and in his 11 interactions with Ms. Hammons made 12 his decisions on. 13 BY MR. MORIARTY: 14 Q. When you're relying on 15 Mrs. Hammons' deposition, are you relying 16 on some visual observations she made or 17 some feeling that she had about the 18 degree of bulge of her cystocele and her 19 apical prolapse? 20 A. Well, first, of course, she 21 doesn't differentiate between a cystocele 22 and apical prolapse. Women experience 23 prolapse. 24 Q. Okay.</p>

25 (Pages 94 to 97)

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<p style="text-align: right;">Page 98</p> <p>1 A. And to my understanding of 2 her deposition testimony, it was a 3 description of what she felt that she 4 described in deposition. 5 Q. Okay. And what you're 6 saying is what she felt, in your opinion, 7 is inconsistent with a Grade 4 cystocele? 8 A. Yes. 9 Q. Okay. Had Dr. Baker chosen 10 anterior colporrhaphy to repair her 11 cystocele instead of Prolift, is it 12 likely that she would have had a 13 recurrence of her cystocele by now? 14 A. So here, I'm going to ask 15 you to -- are you speaking about a 16 general patient who only has an anterior 17 cystocele, or Mrs. Hammons and her 18 situation? 19 Q. Okay. Let me ask it again. 20 We know that she had a 21 vaginal hysterectomy, anterior Prolift, 22 and no apical repair at the time of the 23 May 2009 procedure, correct? 24 A. Correct.</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. Well, when you say in your 2 answer that you just gave that it wasn't 3 treated adequately, you're talking about 4 the failure to do the apical repair, 5 correct? 6 A. Yes. 7 Q. Okay. That put her at 8 higher risk of recurrence no matter which 9 technique he chose, correct? 10 A. Yes, probably. 11 Q. Okay. Had Dr. Baker chosen 12 the combination of vaginal hysterectomy, 13 no apical repair, but used anterior 14 colporrhaphy, is it likely that she still 15 would have suffered a prolapse in the 16 posterior -- in other words, a 17 rectocele -- in 2009 or early 2010? 18 A. I can't answer that. That 19 would be guessing. 20 Q. Okay. Are you going to 21 render any opinions in this case that the 22 anterior Prolift was the cause of her 23 rectocele or enterocele that were 24 detected in the fall of 2009?</p>
<p style="text-align: right;">Page 99</p> <p>1 Q. Okay. Had he chosen vaginal 2 hysterectomy, no apical repair, and an 3 anterior colporrhaphy for the cystocele, 4 is it likely that by now she would have 5 had a recurrence of her cystocele? 6 A. I don't think it's more 7 likely than not. 8 Q. There's a high risk that it 9 would have recurred? 10 MR. SLATER: Objection. 11 That question has been answered. 12 THE WITNESS: It's a very 13 artificial type of question, 14 because you're asking me to try to 15 judge what her risk of anterior 16 vaginal prolapse would be in the 17 setting when her prolapse wasn't 18 necessarily treated adequately. 19 And we talk about the vagina 20 as if it exists in three 21 compartments. But that's not -- 22 that's our designation to make it 23 easier to talk about. 24 BY MR. MORIARTY:</p>	<p style="text-align: right;">Page 101</p> <p>1 A. No. 2 Q. Okay. I want to get back to 3 this exhibit that I think that you have 4 in your left hand. Is that 7, the office 5 visit? 6 A. Yes. 7 Q. On the last page under 8 diagnosis, he's got some shorthand for 9 what looks like an informed consent 10 discussion. Would you agree with me? 11 A. Yes. 12 Q. Okay. And I'm going to read 13 it, and I'm going to interpret it. And 14 you tell me when I'm done if you think 15 that my interpretation is reasonable. 16 And it's based on what he testified to. 17 Okay. Are you ready? 18 He's going to do a 19 vaginal -- total vaginal hysterectomy, 20 bilateral salpingo-oophorectomy, anterior 21 Prolift. Discussed risks and 22 complications including not working; pain 23 with sex; bleeding; infection; injury to 24 bowel, bladder, and ureter.</p>

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<p style="text-align: right;">Page 102</p> <p>1 Based on what you know about 2 this case, is that basically what that 3 says there? 4 A. I don't have a reason to 5 dispute that. Dr. Baker I think read it 6 into the record on his -- in his 7 deposition. So if he had a different 8 interpretation, I would defer to that. 9 Q. And I'm sorry I don't have 10 an extra copy of this, but this is -- 11 MR. MORIARTY: I'll mark 12 this copy as 8. I'm sorry. The 13 word "consent" is highlighted with 14 a date. 15 (Document marked for 16 identification as Exhibit 17 Weber-8.) 18 MR. MORIARTY: It's the 19 admission history and physical 20 from the day of the surgery. 21 We can make an extra copy at 22 a break if you need it, Adam. 23 BY MR. MORIARTY: 24 Q. Doctor, does the consent</p>	<p style="text-align: right;">Page 104</p> <p>1 would have had been receiving and 2 reviewing because of his membership in 3 ACOOG, A-C-O-O-G? 4 MR. SLATER: Objection. 5 Foundation. 6 THE WITNESS: I believe that 7 was his testimony. 8 MR. SLATER: Your question 9 wasn't whether he had seen a 10 specific issue? 11 MR. MORIARTY: No. I asked 12 whether it was a journal that he 13 would have had available to him. 14 MR. SLATER: Okay. 15 BY MR. MORIARTY: 16 Q. Now, obviously, Doctor, 17 you've got lots of writing in your 18 primary report, Exhibit 2, and then in 19 your report in this case, Exhibit 1, with 20 your opinions about how Prolift is 21 defective, correct? 22 A. Yes. 23 Q. I want to make sure that I 24 understand one point about that. Is</p>
<p style="text-align: right;">Page 103</p> <p>1 section say that "I discussed the risks 2 of injury to bleeding and infection, risk 3 of injury to bowel, bladder, or ureters, 4 as well as not being happy with surgery 5 or having pain with intercourse or other 6 types of pain following surgery. The 7 patient has agreed to these risks and 8 wishes to proceed with surgery despite 9 these risks"? Is that what that says at 10 the very bottom of the first page and the 11 top of the second? 12 A. Yes. 13 Q. Okay. Thank you. 14 Now, did you publish in 2005 15 an article with Dr. Richter about 16 diagnosis and treatment of pelvic organ 17 prolapse? 18 A. I would need my CV. I don't 19 have any reason to dispute that. 20 Q. Okay. From your -- we can 21 look at that if you need it. But the 22 point of my question is this. From your 23 understanding of Dr. Baker's deposition, 24 is the Green Journal a journal that he</p>	<p style="text-align: right;">Page 105</p> <p>1 there any published literature that 2 indicates that the complication rate for 3 Prolift is greater than 50 percent? In 4 other words, that the dyspareunia rate is 5 higher than 50 percent or the erosion 6 rate or any other complication? 7 MR. SLATER: Objection. 8 This goes beyond the scope of this 9 deposition. Please ask your next 10 question. 11 BY MR. MORIARTY: 12 Q. Are you going to answer my 13 question? 14 MR. SLATER: Counsel, why 15 are you asking the witness? This 16 is a lawyer decision. The 17 question is beyond the scope of 18 the agreed scope of these 19 depositions. It's a general 20 question that has been covered in 21 other depositions. It's been in 22 her report since day one. Please 23 go to your next question. 24 I'm directing her not to</p>

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<p style="text-align: right;">Page 106</p> <p>1 answer, because there's an 2 agreement on a national level of 3 what the scope of this deposition 4 would be. 5 You asked me to inform you 6 if you went beyond what you were 7 supposed to be doing. You just 8 did. I've been very, very 9 patient. You've asked a lot of 10 general questions. You've asked a 11 lot of things that go beyond this 12 case. I've tried to be patient. 13 This question is point blank 14 outside of the scope of our 15 agreement. 16 Please go to your next 17 question and focus on the patient. 18 MR. MORIARTY: And I believe 19 that as a -- 20 MR. SLATER: I don't want to 21 dispute it. Please go to your 22 next question. 23 MR. MORIARTY: -- as a 24 free-thinking adult and at one</p>	<p style="text-align: right;">Page 108</p> <p>1 address the prolapse in addition to the 2 vaginal hysterectomy in 2009? 3 A. Are we speaking in general 4 terms, or are we speaking specifically? 5 Q. I'll rephrase. Had 6 Dr. Baker chosen vaginal hysterectomy 7 with anterior colporrhaphy, was stress 8 urinary incontinence still a potential 9 risk of that procedure? 10 A. A small risk, yes. 11 Q. Okay. Would the same be 12 true if he had chosen vaginal 13 hysterectomy plus paravaginal repair? 14 A. Yes. 15 Q. And would other forms of 16 incontinence, such as urge incontinence, 17 also have been potential risks, had he 18 chosen those procedures? 19 A. Those are all risks in 20 general, yes. 21 Q. Okay. Do you have some 22 opinion that specifically gives -- I'm 23 sorry. Let me withdraw that. 24 Is it your opinion that the</p>
<p style="text-align: right;">Page 107</p> <p>1 point a licensed physician, she is 2 entitled to make the decision 3 about -- 4 MR. SLATER: She's not. 5 MR. MORIARTY: -- whether 6 she answers the question or not. 7 MR. SLATER: She's not. 8 Because this is a decision and 9 agreement that goes beyond one 10 question at one deposition. 11 MR. MORIARTY: Okay. 12 MR. SLATER: You know better 13 than that. Please move on. 14 You're going to let me joust 15 with your experts and they're 16 going to make the decision whether 17 to answer questions and you're 18 going to stay out of it? I doubt 19 it. Let's just live in reality. 20 Please move on. 21 BY MR. MORIARTY: 22 Q. Was stress urinary 23 incontinence a potential risk of 24 whichever surgery Dr. Baker chose to</p>	<p style="text-align: right;">Page 109</p> <p>1 risk of SUI following Prolift combined 2 with vaginal hysterectomy is higher than 3 it would have been with anterior 4 colporrhaphy or PVR? 5 A. In general. Not -- so we're 6 not speaking specifically of Mrs. Hammons 7 necessarily. In general. 8 Q. Well, sure. 9 A. Yes. That's been reported. 10 Q. Okay. And what's the 11 statistical difference between the risk 12 of SUI with Prolift versus native tissue 13 repair? 14 A. I would need to refer to the 15 specific articles to give you an absolute 16 number. 17 Q. Okay. So specifically for 18 Mrs. Hammons, is it your opinion that 19 choosing the Prolift as opposed to 20 another native tissue repair of her 21 cystocele increased her risk of SUI or 22 another form of incontinence, I should 23 add? 24 MR. SLATER: Objection.</p>

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<p style="text-align: right;">Page 110</p> <p>1 Compound. Foundation. 2 THE WITNESS: I believe the 3 literature supports any form of 4 incontinence after a Prolift 5 procedure is higher than native 6 tissue repairs. 7 BY MR. MORIARTY: 8 Q. But standing here today -- 9 sitting here today, you can't tell me 10 which article or what that rate is? 11 MR. SLATER: Objection -- 12 THE WITNESS: No, I can't 13 pull that off the top of my head. 14 BY MR. MORIARTY: 15 Q. Okay. I want to talk about 16 what information Dr. Baker would have had 17 available to him. 18 We've been going about an 19 hour since the last break. Are you good 20 to keep going? 21 MR. SLATER: I could use a 22 break, actually. 23 THE WITNESS: Yeah, this 24 would be a good time. This is a</p>	<p style="text-align: right;">Page 112</p> <p>1 are general questions about what 2 documents might have been 3 available in the world. 4 I'll see what you ask, but I 5 really think this goes beyond the 6 deposition. 7 BY MR. MORIARTY: 8 Q. Doctor, I handed you what's 9 been marked Exhibit -- is it 9? 10 A. Yes. 11 (Document marked for 12 identification as Exhibit 13 Weber-9.) 14 MR. SLATER: Do you have a 15 copy for me? 16 MR. MORIARTY: I'm sorry. I 17 don't. But I'll -- I can give you 18 this -- 19 MR. SLATER: Do you want to 20 make a proffer as to what it is? 21 MR. MORIARTY: I'm going to 22 ask her. 23 BY MR. MORIARTY: 24 Q. Doctor, do you see the</p>
<p style="text-align: right;">Page 111</p> <p>1 good time for a break. 2 (Short break.) 3 BY MR. MORIARTY: 4 Q. I want to ask you some 5 questions about sources of information 6 that would likely have been available to 7 Dr. Baker at the time he talked to 8 Mrs. Hammons in 2009. 9 MR. SLATER: When you say 10 sources of information available, 11 do you mean that existed in the 12 world? 13 MR. MORIARTY: Yes, sir. 14 MR. SLATER: I see what you 15 have there. And you're not going 16 to be able to lay a foundation to 17 establish what -- of what you most 18 of want to do, if you read the 19 depositions of the corporate reps 20 and the witnesses who were 21 involved in those documents. So 22 I'm not really sure why you're 23 asking her these questions in a 24 case-specific deposition. These</p>	<p style="text-align: right;">Page 113</p> <p>1 fuchsia sticker at the bottom? 2 A. Yes. 3 Q. Okay. This was marked as 4 Exhibit 6 in Dr. Baker's deposition. 5 Okay. 6 A. Okay. 7 Q. All right. So, now, 8 whatever he said is what he said. But if 9 Dr. Baker testified that he had documents 10 like this available, and assuming this 11 one was available in -- by May of 2009 12 when he took her to the operating room, 13 is this the kind of information from 14 which he could draw at least some 15 information about things like the risk of 16 the Prolift device? 17 MR. SLATER: Wait a second. 18 I have an objection. Objection to 19 the form. It's compound. It's 20 overbroad. The foundation is 21 faulty and false. 22 You can answer if you want. 23 BY MR. MORIARTY: 24 Q. Okay.</p>

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<p style="text-align: right;">Page 114</p> <p>1 A. I'm sorry. I lost you in 2 the middle of that question. 3 Q. Okay. Patient brochures, to 4 the extent that a doctor had one 5 available and to the extent that this was 6 available, if it was available to 7 Dr. Baker, this is the kind of thing that 8 he and his patient could use as at least 9 one source of information to discuss 10 risks and complications of the procedure 11 that he proposed, correct? 12 A. Any of his patients, not 13 Mrs. Hammons in particular? 14 Q. Including Mrs. Hammons. 15 MR. SLATER: Objection. 16 THE WITNESS: Well, they're 17 different. 18 MR. SLATER: Same objection 19 I made before. It's a patient 20 brochure. Yes, it is. 21 BY MR. MORIARTY: 22 Q. Okay. 23 A. Is it something that 24 Mrs. Hammons would have seen?</p>	<p style="text-align: right;">Page 116</p> <p>1 want. 2 Q. If the evidence is that 3 Dr. Baker had this document available to 4 him -- 5 A. That specific document? 6 Q. Yeah. It was marked in his 7 deposition, and he was asked about it. 8 MR. SLATER: What does that 9 prove? That's a misleading 10 question, deliberately misleading. 11 You know better than that. 12 BY MR. MORIARTY: 13 Q. All I want to know is if 14 this was available to Dr. Baker and 15 Mrs. Hammons in May of -- March or May of 16 2009, this is the kind of information 17 that was available to give them some 18 information about Prolift and its risks. 19 MR. SLATER: Objection. 20 BY MR. MORIARTY: 21 Q. Yes or no? 22 MR. SLATER: Same series of 23 objections. Your question is, if 24 it was available, would it have</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. Well, that's something that 2 a jury will decide or a judge will decide 3 if this doesn't get proper foundation. 4 The question is, if this was available to 5 Dr. Baker, is this in general the kind of 6 information that he would have had 7 available to discuss with the patient, 8 including like Mrs. Hammons -- 9 MR. SLATER: Objection to 10 the form of the question. 11 BY MR. MORIARTY: 12 Q. -- in May of 2009? 13 MR. SLATER: Objection to 14 the form of the question. No 15 foundation. Do you want to make a 16 proffer that it was given to him, 17 which you know you can't do? 18 THE WITNESS: It's a patient 19 brochure. There were different 20 patient brochures available at 21 different times. 22 BY MR. MORIARTY: 23 Q. I understand that. 24 A. I'm not clear on what you</p>	<p style="text-align: right;">Page 117</p> <p>1 been available? Okay. I object 2 to it for all the reasons I said 3 before. 4 You can answer. 5 THE WITNESS: If it was 6 available, the kind of 7 information, not the exact 8 information, but the kind of 9 information would be something 10 that Dr. Baker would have 11 available to him. 12 (Document marked for 13 identification as Exhibit 14 Weber-10.) 15 BY MR. MORIARTY: 16 Q. Exhibit 10. 17 (Whereupon, a discussion was 18 held off the record.) 19 BY MR. MORIARTY: 20 Q. Doctor, how did you become 21 available -- how did you become aware of 22 Exhibit 10, the 2008 FDA notice? 23 MR. SLATER: Objection. 24 Don't answer the question.</p>

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<p style="text-align: right;">Page 118</p> <p>1 Please ask about the Hammons 2 case. 3 Next question. 4 BY MR. MORIARTY: 5 Q. Was the 2008 FDA notice 6 reasonably available to operating 7 surgeons in 2009? 8 MR. SLATER: Objection to 9 the form of the question. 10 You can answer. 11 THE WITNESS: Yes. 12 BY MR. MORIARTY: 13 Q. To the best of your 14 knowledge, was there published 15 information available about dyspareunia 16 rates with pelvic mesh kits by May of 17 2009? 18 MR. SLATER: Objection. 19 Don't answer the question. It's a 20 general question. It's not -- not 21 geared to this case. Please move 22 on. 23 (Document marked for 24 identification as Exhibit</p>	<p style="text-align: right;">Page 120</p> <p>1 available to Dr. Baker by virtue of his 2 membership in the American College of 3 Obstetrics and Gynecology, the D.O. 4 division, osteopathic? 5 MR. SLATER: Objection. 6 THE WITNESS: Yes. 7 BY MR. MORIARTY: 8 Q. Handing you Exhibit 12. 9 (Document marked for 10 identification as Exhibit 11 Weber-12.) 12 BY MR. MORIARTY: 13 Q. Have you ever seen this 14 document before? 15 A. Yes. 16 Q. Okay. This is Dr. Lowman's 17 paper entitled "Does the Prolift System 18 Cause Dyspareunia?" 19 Is that the name of it? 20 A. Yes. 21 Q. Was it published in 2008? 22 A. Yes. 23 Q. Was it published in the 24 American Journal of Obstetrics &</p>
<p style="text-align: right;">Page 119</p> <p>1 Weber-11.) 2 BY MR. MORIARTY: 3 Q. I'm handing you Exhibit 11. 4 MR. SLATER: Are you 5 ignoring my objection? 6 MR. MORIARTY: No. I'm 7 going to ask a more specific 8 question. 9 BY MR. MORIARTY: 10 Q. Is this article about 11 dyspareunia and mesh erosion after 12 vaginal mesh placement with a kit 13 procedure? 14 A. Yes, that is the title. 15 Q. Was it published in April of 16 2008? 17 A. Yes. 18 Q. In Obstetrics & Gynecology? 19 A. Yes. 20 Q. And that is The Green 21 Journal? 22 A. Yes. 23 Q. And is this the kind of 24 information that would have been</p>	<p style="text-align: right;">Page 121</p> <p>1 Gynecology? 2 A. Yes. 3 Q. Would this information have 4 been available to you when it was 5 published in 2008? 6 A. Yes. 7 Q. Was this kind of information 8 generally available to doctors who were 9 operating on the pelvic floor in 2008 and 10 2009? 11 MR. SLATER: Objection. 12 THE WITNESS: It was 13 generally available. 14 (Document marked for 15 identification as Exhibit 16 Weber-13.) 17 BY MR. MORIARTY: 18 Q. Okay. Doctor, is this -- 19 Exhibit 13, is this an ACOG practice 20 bulletin from September 2007? 21 A. Yes. 22 Q. About pelvic organ prolapse? 23 A. Yes. 24 Q. And did you -- I don't know</p>

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<p style="text-align: right;">Page 122</p> <p>1 if "collaborate" is the right word. Were 2 you involved in the drafting of this 3 document? 4 A. Yes. 5 Q. Would Dr. Baker, because of 6 his membership in ACOOG, have been aware 7 of this kind of information when it was 8 published? 9 MR. SLATER: Objection. 10 THE WITNESS: This was 11 published in The Green Journal 12 which he said he received. 13 BY MR. MORIARTY: 14 Q. And I know at one point 15 there was an ACOG bulletin about which 16 you wrote a letter to the editor, and 17 there was an exchange back and forth. Is 18 this the ACOG bulletin that was the 19 subject of that letter to the editor? 20 A. No. This is the revised. 21 Q. Okay. That's all I had to 22 ask you about that. 23 MR. SLATER: Oh, it's the 24 same bulletin. It's just the</p>	<p style="text-align: right;">Page 124</p> <p>1 you about an opinion that you wrote at 2 Page -- Pages 9 through 10 of your report 3 in this case, Exhibit 1. It's about this 4 training issue. 5 A. Yes. 6 Q. Do you have that there? 7 Now, Doctor, I don't know 8 the extent to which you have been 9 questioned about training issues that you 10 wrote in your primary report, Exhibit 2. 11 Okay. So I'm sure Mr. Slater will tell 12 me if I'm asking questions that you've 13 already been asked about, but I need to 14 understand this -- 15 MR. SLATER: Counsel, if 16 your questions are specific to 17 this case, as I've been doing, I'm 18 not going to object. If you're 19 going to ask general questions on 20 a report that's been out for three 21 and a half years, a little over 22 three years, you know, I'd rather 23 you not do it, because I'm going 24 to have to keep stopping her from</p>
<p style="text-align: right;">Page 123</p> <p>1 revised version. 2 THE WITNESS: Correct. 3 BY MR. MORIARTY: 4 Q. Well, when you say "revised 5 version," what do you mean? 6 A. I mean that this was 7 published in September 2007 after 8 replacing a practice bulletin that was 9 published in February 2007, meaning this 10 is not the original practice bulletin; 11 this is the revised practice bulletin. 12 Q. Okay. To the best of your 13 knowledge, were there any limitations on 14 Dr. Baker's privileges to practice 15 surgery at Daviess Community Hospital? 16 A. I have no knowledge of that. 17 Q. All right. Is the hospital 18 the entity that typically would 19 credential someone like Dr. Baker and lay 20 out the type of procedures they are 21 allowed to perform and not allowed to 22 perform? 23 A. Yes. 24 Q. All right. I want to ask</p>	<p style="text-align: right;">Page 125</p> <p>1 answering. 2 We have an agreement that 3 this is supposed to be a 4 case-specific deposition. She's 5 been deposed. And more important, 6 Ethicon lawyers have had the 7 opportunity to depose Dr. Weber 8 for days and days and days on 9 multiple cases on her opinions. 10 MR. MORIARTY: I understand 11 that. But this opinion is 12 different. 13 MR. SLATER: Well, let's see 14 what you ask. If you're going to 15 ask general testimony, I'm not 16 going to let her answer, because 17 there's an agreement on this. 18 BY MR. MORIARTY: 19 Q. Is it true that drug and 20 device manufacturers don't control how 21 Dr. Baker conducts his medical practice? 22 MR. SLATER: Objection. 23 THE WITNESS: The influence 24 that Ethicon has on a doctor like</p>

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<p style="text-align: right;">Page 126</p> <p>1 Dr. Baker is to select him for 2 training and lead him to believe 3 that he is qualified to perform 4 the Prolift surgeries, when, 5 according to their own internal 6 standards, they were looking 7 for -- they were targeting doctors 8 who had high volume, were 9 experienced pelvic floor surgeons. 10 According to those criteria, he 11 does -- he does not meet those 12 criteria. 13 BY MR. MORIARTY: 14 Q. Okay. I understand that's 15 the opinion in your report. I'm asking a 16 different question. 17 When it comes to Dr. Baker's 18 decision about what drugs to prescribe or 19 devices to prescribe for his patients, 20 it's not the drug or device manufacturers 21 that control whether he does those things 22 or doesn't do those things, correct? 23 MR. SLATER: Objection. You 24 can answer.</p>	<p style="text-align: right;">Page 128</p> <p>1 didn't have to seek the permission of a 2 device company every time he did that, 3 did he? 4 A. No. 5 Q. Do you know what percentage 6 of surgeons perform Prolift, for example, 7 who never underwent the Ethicon-offered 8 training? 9 A. No. 10 Q. Even had Dr. Baker not 11 undergone the training, could he have 12 still used and prescribed the Prolift 13 device? 14 A. My understanding of 15 Dr. Baker's testimony was that he would 16 not go rogue and use devices without that 17 kind of training. The problem with the 18 training was that first it led him to 19 believe that he was qualified, and 20 provided him with inaccurate and 21 misleading information about how -- what 22 outcomes to expect from his patients, 23 which he then provided to his patients, 24 believing it to be true.</p>
<p style="text-align: right;">Page 127</p> <p>1 THE WITNESS: He was 2 approached by sales 3 representatives and told he was 4 qualified to perform this 5 procedure and underwent -- to 6 perform the Prolift procedures, 7 and then underwent Ethicon's 8 training where they reinforced to 9 him that he was a suitable 10 candidate to perform Prolift 11 procedures in spite of what 12 they -- what their internal 13 documents show. 14 BY MR. MORIARTY: 15 Q. Okay. But when it comes to 16 actually prescribing the Prolift device 17 for a patient or not, that is up to the 18 judgment of Dr. Baker; isn't that true? 19 A. It's up to the judgment of 20 Dr. Baker based on the information that 21 he'd received during his training, which 22 is inaccurate and misleading. 23 Q. When Dr. Baker performed 24 surgery using any medical device, he</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. Okay. To the best of your 2 understanding, there's no requirement by 3 Indiana state law, Indiana regulation, 4 FDA regulation, anything that would 5 legally apply to Dr. Baker that would 6 require him to undergo Ethicon training; 7 is that true? 8 A. Yes. 9 Q. Okay. I understand that 10 your opinion about which doctors should 11 have been trained and should not have 12 been trained is based on company 13 documents and, I think, testimony from 14 company witnesses. I'm correct, am I 15 not? 16 A. Yes. 17 Q. Okay. Is there any other 18 source of information that forms the 19 basis for your opinion that Dr. Baker 20 should not have been trained on Prolift 21 other than company documents and the 22 testimony of company witnesses? 23 A. No. 24 Q. In other words, you're not</p>

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<p style="text-align: right;">Page 130</p> <p>1 relying on any guidelines from ACOG or 2 AUGS or another organization like that 3 for the basis of this particular opinion 4 that we're talking about? 5 A. Well, they referred to -- 6 those guidelines that you point out do 7 refer to doctors having experience with 8 treating women with prolapse, so that 9 there -- those guidelines do exist and, 10 as guidelines, offer some guidelines -- 11 I'm sorry. 12 They help define who's most 13 qualified based on experience and 14 training to perform reconstructive 15 surgery. 16 Q. Do those guidelines set 17 volume limits, X number of procedures per 18 month or year? 19 A. No, not those guidelines. 20 In the literature, there are studies of 21 the learning curve and how long it takes 22 to perform certain difficult -- 23 technically difficult procedures. But, 24 no, those numbers are not in the</p>	<p style="text-align: right;">Page 132</p> <p>1 A. I think they're 2 interrelated. 3 Q. Do you have any evidence 4 from any source in this case to indicate 5 that Dr. Baker was not skilled when he 6 performed Prolift procedures? 7 MR. SLATER: Objection. You 8 can answer. 9 THE WITNESS: The only 10 information I have specific to 11 that is Mrs. Hammons. And she did 12 not experience any acute 13 intraoperative complications. 14 BY MR. MORIARTY: 15 Q. Okay. Now, I'll get back 16 later to what complications you believe 17 she did suffer as a result of the 18 May 2009 procedure. But quickly tell me 19 what complications you believe she did 20 suffer from that surgery. 21 A. She experienced progressive 22 Prolift mesh contraction that resulted in 23 vaginal anatomic distortion, pain, such 24 severe pain with intercourse that she has</p>
<p style="text-align: right;">Page 131</p> <p>1 guidelines. 2 Q. Okay. And just because 3 Dr. Baker lives and practices surgery in 4 a rural part of southern Indiana doesn't 5 automatically mean that he's not a 6 skilled surgeon, true? 7 A. His volume of prolapse 8 surgeries is very low. 9 MR. SLATER: Dr. Weber, the 10 question was just because he's in 11 rural Indiana. That's all that 12 was asked, right? 13 MR. MORIARTY: Yes. 14 MR. SLATER: Please stick to 15 the question. 16 THE WITNESS: I'm sorry. 17 No, that does not reflect on his 18 skill as a surgeon. 19 BY MR. MORIARTY: 20 Q. Okay. And tell me what, in 21 your opinion -- does the volume of 22 procedures increase the skill level, or 23 is it the familiarity level, or are those 24 two interrelated?</p>	<p style="text-align: right;">Page 133</p> <p>1 apareunia, vaginal mesh erosion, and 2 bladder mesh erosion. 3 MR. SLATER: Could you read 4 that back? 5 (Whereupon, the court 6 reporter read back the requested 7 portion of testimony.) 8 MR. SLATER: Thank you. 9 BY MR. MORIARTY: 10 Q. In your opinion, are all of 11 those complications related to the mesh 12 or the transvaginal placement of the 13 mesh, or are any of them related to a 14 surgical technique issue or a skill 15 issue? 16 A. The surgical technique issue 17 and the characteristics of the mesh. 18 Q. What do you mean by "the 19 surgical technique issue"? 20 A. Because of the way mesh 21 contracts during healing -- for example, 22 hernia repair surgeons have learned they 23 must overlap the boundaries of the hernia 24 by at least five centimeters to account</p>

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<p style="text-align: right;">Page 134</p> <p>1 for the kinds of contractions that occur. 2 In -- 3 Q. Okay. I don't mean to cut 4 you off. What I'm trying to get at with 5 this particular question -- and I 6 understand that you think that the use of 7 transvaginal mesh kits is defective and 8 it shouldn't have been done here. Okay. 9 What I'm trying to figure 10 out is if it's the Prolift that caused 11 these complications that you just 12 mentioned or a specific lack of surgical 13 skill by Dr. Baker. 14 A. Okay. I understood your 15 question as surgical technique to refer 16 to the surgery -- 17 Q. No. 18 A. -- the technique of the 19 Prolift itself. 20 The problem with the 21 surgical technique -- 22 MR. SLATER: Dr. Weber, all 23 he's asking is are you saying 24 Baker did it wrong, or are you</p>	<p style="text-align: right;">Page 136</p> <p>1 itself, like the tension-free aspects and 2 how he would -- could have been trained 3 or not trained on that, because there's 4 no agreed-upon definition of tension. 5 But as I said, during the 6 operation, she did not experience any 7 acute complications. 8 Q. Well, did she experience any 9 chronic complications that you would, to 10 a probability, attribute to his lack of 11 surgical skill? 12 A. No. It's not a surgical 13 skill issue specifically. 14 Q. Just to put it another way, 15 and to make sure -- 16 MR. SLATER: We don't need 17 to put it another way. We spent 18 ten minutes on it. Come on. 19 Let's move on. 20 BY MR. MORIARTY: 21 Q. To make sure I understand -- 22 MR. SLATER: If you don't 23 really understand that, Counsel -- 24 really? You really don't</p>
<p style="text-align: right;">Page 135</p> <p>1 saying that the Prolift procedure 2 is unsafe. That's all he wants to 3 know. 4 THE WITNESS: I'm saying the 5 Prolift procedure is unsafe in 6 terms of what happens 7 postoperatively. 8 BY MR. MORIARTY: 9 Q. Okay. I understand that. 10 I'm just trying to find out whether you 11 have an opinion in this case that a 12 particular aspect of Dr. Baker's surgical 13 skill was the result -- I'm sorry -- was 14 the cause of any of the complications 15 that you listed. Okay? Not the Prolift 16 device or the mesh itself, a particular 17 aspect of his surgical skill or lack 18 thereof. 19 A. At least according to the 20 operative note as written, he performed 21 the Prolift procedure the way he had been 22 taught, trained by Ethicon. 23 That doesn't take into 24 account the problems with the technique</p>	<p style="text-align: right;">Page 137</p> <p>1 understand that? 2 MR. MORIARTY: Okay. That's 3 fine. 4 BY MR. MORIARTY: 5 Q. I don't remember what 6 exhibit this was, Doctor. This was 7 Dr. Baker's operative note. Exhibit 6. 8 On the second page, I just 9 have a couple questions about this. He 10 says, "A midline incision was made," 11 talking about the section where he's 12 going to do the Prolift. 13 Do you see that? 14 A. Yes. 15 Q. And based on this report, 16 where do you understand that incision to 17 be in relationship with any incisions he 18 made for the hysterectomy? 19 A. The midline incision's made 20 in the anterior vagina, from the point 21 outside distal -- nearest the urethral 22 natus to the vaginal cuff along the 23 anterior wall. 24 The incision that's made in</p>

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<p style="text-align: right;">Page 138</p> <p>1 the hysterectomy is typically 2 circumferential around the cervix itself. 3 Q. And is that at the -- 4 considered to be in the posterior portion 5 of the vagina? 6 A. No. That would be the apex. 7 Q. Okay. On the second page, 8 it says, "There was a small hole noted in 9 the membrane between that plane and the 10 intra-abdominal cavity which was closed 11 with purse-string 2-0 Vicryl." 12 What is your understanding 13 of where that hole was and through what 14 planes? 15 A. The hole was in the 16 peritoneum, so the peritoneal membrane is 17 what he's describing there. 18 Q. All right. And then a few 19 lines down it says, "There was a lot of 20 fluid that was draining into the vagina." 21 Do you have an opinion as to 22 what the source of that fluid was? 23 A. It's not something that I 24 can say with certainty from his operative</p>	<p style="text-align: right;">Page 140</p> <p>1 Dr. Baker's partner also was a user of 2 Prolift? 3 A. I don't recall that 4 specifically from the deposition 5 testimony, whether it was specific to 6 Prolift or a different type of mesh 7 procedure. 8 Q. Okay. We're talking about 9 this Dr. Francis who assisted in the 10 procedure? 11 A. Yes. 12 Q. Do you know whether 13 Dr. Lackey's partners are users of 14 transvaginal mesh products? 15 A. I don't know. 16 Q. You know Dr. Heit was, 17 correct? 18 A. A user of mesh procedures? 19 Q. Yes. Transvaginal mesh 20 procedures in 2009. 21 A. Yes, I believe so, yeah. 22 Q. Was Dr. Heit the first 23 physician to measure the dimensions of 24 Mrs. Hammons' vagina in 2012?</p>
<p style="text-align: right;">Page 139</p> <p>1 report. 2 Q. Do you have an opinion, to a 3 probability? 4 A. No. 5 Q. Do you have a list of 6 differential possibilities for the source 7 of that fluid? 8 A. The differential would be 9 the bladder and the intraperitoneal 10 cavity. 11 Q. What fluid would drain from 12 the intraperitoneal cavity all the way 13 into the vagina in a procedure like this? 14 A. Well, he has the closure of 15 the peritoneum that -- through a Vicryl 16 suture. It's not something that's 17 watertight. There's a certain amount of 18 fluid that's in the intra-abdominal 19 cavity that could come through that. 20 Obviously, there's no characterization of 21 the volume other than "a lot of fluid." 22 Q. Okay. Was it your 23 understanding that Dr. Lackey -- I'm 24 sorry. Was it your understanding that</p>	<p style="text-align: right;">Page 141</p> <p>1 A. Yes. 2 Q. And by then, Mrs. Hammons 3 had had the vaginal hysterectomy, 4 anterior Prolift, and a posterior repair 5 by Dr. Lackey? 6 A. Yes. 7 Q. Is it likely that the 8 combination of a vaginal hysterectomy, 9 any type of anterior repair for a 10 cystocele, and a posterior repair for a 11 rectocele/enterocele, would shorten the 12 vagina? 13 A. We're speaking in general? 14 Q. Yes. 15 A. There's a risk of that. 16 Q. Okay. And that risk would 17 apply to Mrs. Hammons? 18 A. It would apply to 19 Mrs. Hammons. We have the evidence from 20 Dr. Heit's exam regarding abnormalities 21 he found in the anterior vagina related 22 to the Prolift mesh where it was tense 23 and taut, and the mesh contraction would 24 be contributing based on his exam to the</p>

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<p style="text-align: right;">Page 142</p> <p>1 shortened vaginal length at that point. 2 Q. Did Dr. Heit mention in his 3 records or in his deposition that it was 4 his opinion that the shortened vagina was 5 multifactorial? 6 A. Yes, I believe that was his 7 deposition testimony. 8 Q. Would Mrs. Hammons, by 9 virtue of her age and her menopausal 10 status, would that also increase the risk 11 of her having a shortened vagina? 12 A. No. I don't believe so. 13 Q. Why not? 14 A. In my clinical experience, 15 only a severe atrophy that occurs in 16 women who are much farther past their age 17 of menopause results in a change in the 18 vaginal dimensions. For someone like 19 Mrs. Hammons, the atrophy is more 20 superficial and related to the changes in 21 the epithelium of the vagina. 22 Q. How many years was she 23 postmenopause by May of 2009? 24 A. I don't remember exactly.</p>	<p style="text-align: right;">Page 144</p> <p>1 Dr. Zipper's report, she wasn't having 2 urinary incontinence at the time he saw 3 her. So whether that had anything to do 4 with stress incontinence symptoms she had 5 in between, I can't say that with 6 certainty. 7 Q. Okay. And she didn't 8 actually complain of stress urinary 9 incontinence until after Dr. Lackey 10 performed his posterior repair, correct? 11 A. I would have to see the 12 records to answer that with certainty. 13 Q. One quick question about 14 Exhibit 10, which is that FDA statement 15 in 2008. At the bottom of the first 16 page, there are some recommendations, 17 correct? 18 A. Yes. 19 Q. And FDA did not recommend 20 that the procedure be -- the Prolift 21 procedure be restricted to -- I'm sorry. 22 Let me withdraw that question. 23 FDA's notification was not 24 just about one specific company's</p>
<p style="text-align: right;">Page 143</p> <p>1 It would be less than ten. 2 Q. Is ten about the time that 3 the risk of vaginal shortening begins 4 secondary to menopause? 5 A. In my clinical experience, 6 I've seen that in -- in elderly women, 7 70 plus. 8 Q. Okay. 9 A. If this is a good stopping 10 point, perhaps we can take a break. 11 Q. Sure. 12 (Short break.) 13 BY MR. MORIARTY: 14 Q. Sorry to circle back on two 15 things that I forgot about before. I 16 want to go back to what I was asking you 17 about, stress urinary incontinence after 18 Prolift. And I think you said in general 19 you -- your opinion is that Prolift 20 increased the risk of SUI over native 21 tissue repairs. 22 Is it your opinion that it 23 increased the risk for Mrs. Hammons? 24 A. To my understanding, from</p>	<p style="text-align: right;">Page 145</p> <p>1 product, correct? 2 A. Correct. 3 Q. And these recommendations 4 didn't include that only high-volume 5 surgeons should be trained on the 6 procedure -- 7 MR. SLATER: Objection. 8 BY MR. MORIARTY: 9 Q. -- and perform the 10 procedure, correct? 11 MR. SLATER: Objection. Why 12 are we going through this, sir? 13 Sir, please don't ignore 14 that I'm talking to you. I never 15 appreciate that. 16 MR. MORIARTY: Because my 17 answer is not going to satisfy 18 you. 19 MR. SLATER: I don't 20 understand why you are questioning 21 her about a PHN that she wrote 22 about three years ago when she's 23 been deposed about it already. I 24 don't understand why you're doing</p>

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<p style="text-align: right;">Page 146</p> <p>1 this.</p> <p>2 MR. MORIARTY: Because this</p> <p>3 was available before Dr. Baker</p> <p>4 operated.</p> <p>5 MR. SLATER: So what? She's</p> <p>6 been deposed on it.</p> <p>7 MR. MORIARTY: Just either</p> <p>8 tell her to answer or not.</p> <p>9 MR. SLATER: Please move on</p> <p>10 to something that's case-specific.</p> <p>11 BY MR. MORIARTY:</p> <p>12 Q. In 2009, were reasonably</p> <p>13 prudent pelvic surgeons like Dr. Baker</p> <p>14 performing Prolift procedures?</p> <p>15 A. Surgeons were performing</p> <p>16 Prolift procedures based on -- yes, they</p> <p>17 were.</p> <p>18 Q. Okay. So Dr. Baker was not</p> <p>19 committing malpractice when he used</p> <p>20 Prolift on Mrs. Hammons, correct?</p> <p>21 A. I'm not giving</p> <p>22 standard-of-care opinions on Dr. Baker.</p> <p>23 Q. Okay. Either way, that he</p> <p>24 was or was not within the standard of</p>	<p style="text-align: right;">Page 148</p> <p>1 procedure in December of 2009, the</p> <p>2 Prolift was at least managing</p> <p>3 Mrs. Hammons cystocele, correct?</p> <p>4 A. She did not have a recurrent</p> <p>5 cystocele at this point. That's correct.</p> <p>6 Q. Okay. From your</p> <p>7 understanding of Dr. Heit's operative</p> <p>8 notes -- and I will mark them -- did he</p> <p>9 ever actually perform an anterior</p> <p>10 prolapse procedure?</p> <p>11 (Document marked for</p> <p>12 identification as Exhibit</p> <p>13 Weber-15.)</p> <p>14 BY MR. MORIARTY:</p> <p>15 Q. So 15 is his 2012 procedure.</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 Weber-16.)</p> <p>19 BY MR. MORIARTY:</p> <p>20 Q. And 16 is the January 2013</p> <p>21 procedure.</p> <p>22 So you're looking at the one</p> <p>23 from November 28, 2012?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 147</p> <p>1 care, correct? You're giving no opinion</p> <p>2 about that subject?</p> <p>3 MR. SLATER: That's correct.</p> <p>4 THE WITNESS: Correct.</p> <p>5 MR. SLATER: She's not</p> <p>6 proffered on standard of care.</p> <p>7 BY MR. MORIARTY:</p> <p>8 Q. Okay. Did Dr. Lackey's</p> <p>9 procedure --</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Weber-14.)</p> <p>13 BY MR. MORIARTY:</p> <p>14 Q. I'll give you this operative</p> <p>15 report if you need to refresh your</p> <p>16 memory. We're up to 14. This is</p> <p>17 Dr. Lackey's procedure note from</p> <p>18 December 15, 2009.</p> <p>19 A. Yes.</p> <p>20 Q. All right. And did</p> <p>21 Dr. Lackey perform any sort of anterior</p> <p>22 repair during this procedure?</p> <p>23 A. No.</p> <p>24 Q. So at the time of this</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. Did he -- as far as you can</p> <p>2 tell from this operative report, did he</p> <p>3 perform any sort of anterior support</p> <p>4 procedure?</p> <p>5 A. No, he did not.</p> <p>6 Q. Okay. And his pre- and</p> <p>7 postoperative diagnosis didn't include</p> <p>8 any recurrent cystocele, did they?</p> <p>9 A. No.</p> <p>10 Q. And the same is true of the</p> <p>11 January 28, 2013, procedure?</p> <p>12 A. Yes.</p> <p>13 Q. You're not claiming in this</p> <p>14 case, are you, that Mrs. Hammons has</p> <p>15 chronic hip, knee, or lower back pain as</p> <p>16 a result of a Prolift procedure, are you?</p> <p>17 A. No.</p> <p>18 Q. Other than what we've</p> <p>19 already discussed about the lack of an</p> <p>20 apical repair and understanding that you</p> <p>21 have not yourself actually performed a</p> <p>22 Prolift procedure, is there anything in</p> <p>23 Dr. Baker's operative note of May 2009</p> <p>24 that stands out to you as unusual or</p>

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<p style="text-align: right;">Page 150</p> <p>1 inappropriate?</p> <p>2 A. No.</p> <p>3 Q. And is the same true with</p> <p>4 his description of the hysterectomy?</p> <p>5 A. Yes.</p> <p>6 Q. Dr. Baker's first post-op</p> <p>7 office visit was May 17, 2009. And I</p> <p>8 believe at that point in your report you</p> <p>9 mentioned that she was having some</p> <p>10 complaints of urinary problems.</p> <p>11 Was it appropriate for him</p> <p>12 to tell her at that point essentially to</p> <p>13 give it more time?</p> <p>14 May 17, 2009.</p> <p>15 A. Okay. Yes.</p> <p>16 Q. And did whatever urinary</p> <p>17 symptoms she complained about on May 17,</p> <p>18 2009, seem to resolve over the course of</p> <p>19 the next few office visits?</p> <p>20 A. Yes.</p> <p>21 Q. In June -- I'm sorry. On</p> <p>22 June 9, 2009, I think Dr. Baker's office</p> <p>23 note reflects that he was seeing a</p> <p>24 suture. Is it your opinion that that</p>	<p style="text-align: right;">Page 152</p> <p>1 problem with the anterior mesh, which</p> <p>2 would include a contraction, infection.</p> <p>3 She could possibly have a pelvic</p> <p>4 infection that he was feeling a</p> <p>5 tenderness at that point.</p> <p>6 Q. Anything else?</p> <p>7 A. Those are the main ones, I</p> <p>8 think.</p> <p>9 Q. To the best of your</p> <p>10 understanding from these medical records</p> <p>11 and the testimony, she did not have</p> <p>12 either a mesh infection or a pelvic</p> <p>13 infection at that point; is that true?</p> <p>14 A. Yes.</p> <p>15 Q. Were there any complaints of</p> <p>16 dyspareunia recorded in the medical</p> <p>17 records -- withdraw that question.</p> <p>18 Were there any complaints of</p> <p>19 dyspareunia recorded in the medical</p> <p>20 records between Dr. Lackey's procedure in</p> <p>21 December of 2009 and January of 2012?</p> <p>22 I'm just referring to what was recorded</p> <p>23 in the medical records.</p> <p>24 A. So, in my report, I'm just</p>
<p style="text-align: right;">Page 151</p> <p>1 was, in fact, a non -- as of then,</p> <p>2 not-yet-absorbed suture?</p> <p>3 A. I can only go by his</p> <p>4 records. If he reported that he saw a</p> <p>5 suture, it's probably a suture.</p> <p>6 Q. Okay. It's not your opinion</p> <p>7 that she had a vaginal mesh exposure at</p> <p>8 that point, June of 2009?</p> <p>9 A. No.</p> <p>10 Q. So on July 20th of 2009,</p> <p>11 Mrs. Hammons complains to Dr. Baker about</p> <p>12 dyspareunia, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And Dr. Baker writes in his</p> <p>15 note, "This was mostly at the back cuff."</p> <p>16 Did he not?</p> <p>17 A. On the back cuff, yes.</p> <p>18 Q. What is the differential</p> <p>19 diagnosis, in your opinion, for the</p> <p>20 causes of that dyspareunia at that</p> <p>21 location on July 20, 2009?</p> <p>22 A. The differential diagnosis</p> <p>23 would include tenderness from the scar</p> <p>24 from the hysterectomy, tenderness from a</p>	<p style="text-align: right;">Page 153</p> <p>1 referring to records from Dr. Lackey.</p> <p>2 Q. I'm sorry. Could you tell</p> <p>3 me what page you're looking at?</p> <p>4 A. I'm on Page 3 at the bottom,</p> <p>5 which is the July 20, 2009, with</p> <p>6 Dr. Baker.</p> <p>7 Q. Okay.</p> <p>8 A. And you're asking about the</p> <p>9 time -- I'm sorry. Could you remind me</p> <p>10 of the time frame that you're asking</p> <p>11 about?</p> <p>12 Q. Yeah. My question was</p> <p>13 between Dr. Lackey's procedure in</p> <p>14 December of 2009 and January of 2012.</p> <p>15 A. January of 2009?</p> <p>16 Q. No. Between Dr. Lackey's</p> <p>17 surgery of December 2009 and January of</p> <p>18 2012, is there any voiced complaint in</p> <p>19 the medical records of dyspareunia?</p> <p>20 A. I gotcha. In my report, I'm</p> <p>21 just referring to Dr. Lackey. And I</p> <p>22 don't have the information from</p> <p>23 Dr. Rohrer as to whether she reported</p> <p>24 that to him in that time period.</p>

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<p style="text-align: right;">Page 154</p> <p>1 Q. Okay. So as of right now, 2 you don't know the answer? 3 A. Correct. 4 Q. Okay. Let me go back to 5 July 20th of 2009. In your report, you 6 gave the opinion that the most likely 7 cause of her dyspareunia at that point 8 was mesh contraction; is that right? 9 A. Yes. 10 Q. And do you have an opinion, 11 to a reasonable degree of medical 12 probability, as to the degree of that 13 contraction at that point? 14 A. Not a specific degree. 15 Q. Had somebody operated on her 16 at that point and removed the mesh, would 17 it have been flat, folded, bunched? Do 18 you have an opinion on that? 19 A. She's experiencing pain at a 20 location where the mesh arms are 21 inserting into the pelvic side wall. So 22 the Prolift mesh contraction that was 23 going on at that point leading to that 24 pain, I believe that the findings, if</p>	<p style="text-align: right;">Page 156</p> <p>1 a predictable course over the next 2 several years where the 3 contraction becomes more and more 4 evident, until we reach Dr. Heit's 5 exam where he finds that the 6 anterior vagina is tense and taut 7 and tender as the cause of her 8 dyspareunia. 9 BY MR. MORIARTY: 10 Q. Okay. As a complaint of 11 dyspareunia, just as a subjective 12 complaint, was it, I guess, stable from 13 the summer of 2009 up until Dr. Heit saw 14 her in the summer of 2012? 15 A. Mrs. Hammons reported in her 16 deposition testimony that after the 17 Prolift procedure, she was never able to 18 complete the act of sexual intercourse. 19 Her physical findings on examination 20 changed over time as the degree of mesh 21 contraction became more severe. 22 Q. They changed how? Her 23 physical findings changed how? 24 A. They changed from when</p>
<p style="text-align: right;">Page 155</p> <p>1 someone took that out, would represent 2 the bridging fibrosis and the scar 3 plating that happens with mesh 4 contraction. 5 Q. Okay. So you don't have an 6 opinion, to a probability, that there was 7 folding of the mesh or bunching of the 8 mesh as of July of 2009? 9 MR. SLATER: Objection. 10 Mischaracterization. Foundation. 11 THE WITNESS: Well, we know 12 from reports in the literature 13 what contraction looks like. 14 Mrs. Hammons didn't have that kind 15 of an evaluation. 16 But based on her symptoms at 17 that point and then the course 18 that she followed over the next 19 several years, that definitively 20 demonstrated mesh contraction. 21 At this point, she's having 22 some degree of mesh contraction 23 that's responsible for her 24 dyspareunia. And then it follows</p>	<p style="text-align: right;">Page 157</p> <p>1 Dr. Baker initially felt the tenderness 2 at the apex of the vagina, which is where 3 the top anterior body of the Prolift mesh 4 is, and the two deep mesh arms of the 5 Prolift. 6 Dr. Lackey, who palpated 7 mesh in the anterior vagina, and then 8 Dr. Heit, who not only palpated the mesh 9 as being contracted and a source of her 10 pain, he found at surgery that it had 11 contracted to such an extent that it was 12 bunched and rolled and crumpled 13 underneath the latter base of the 14 urethra, not extending the length of the 15 anterior vagina as it was intended to do. 16 Q. Did Dr. Heit testify that 17 that's because of contraction? 18 A. Yes, I believe he did. 19 Q. In your answer, you said 20 definitive demonstration of mesh 21 contraction. 22 What are you referring to 23 was definitively demonstrated that there 24 was mesh contraction?</p>

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<p style="text-align: right;">Page 158</p> <p>1 A. Dr. Heit's description on 2 his examination, Dr. Heit's findings in 3 the operating room, the fact that the 4 mesh was so contracted and causing 5 distortion and adherence under the 6 bladder base that he injured the bladder 7 twice in the course of trying to remove 8 the Prolift mesh, and the pathology 9 findings that describe the gross 10 specimens as rubbery and firm, which is a 11 description that's classic for the 12 bridging fibrosis scar plating that 13 happens with the Prolift mesh. 14 Q. Okay. Is there any 15 diagnosis actually in the medical records 16 of contraction? Did anybody write that 17 as a diagnosis in the medical records? 18 A. I would have to look to see 19 if the exact word exists. 20 Q. Did anybody write the word 21 or words "roping," "fraying," or 22 "degradation of mesh" in Mrs. Hammons' 23 medical records? 24 A. Not to my knowledge, no.</p>	<p style="text-align: right;">Page 160</p> <p>1 BY MR. MORIARTY: 2 Q. In the same study? 3 A. Yes. 4 Q. Okay. 5 A. And this was a study of 6 ultrasound signs of mesh contraction in 7 women after the Prolift procedure. 8 And they found that 9 87 percent of women had moderate to 10 severe retraction by ultrasound, and they 11 described that as crumpled, folded, 12 bunched. They measured the mesh 13 thickness and found that the mesh 14 thickness increased in a direct 15 relationship with the level of mesh 16 retraction. 17 And in addition, we know 18 that these same patients experienced a 19 painful mesh contraction of more than 20 19 percent. So these are the ultrasound 21 and clinical findings that are exactly 22 what happened to Ms. Hammons. 23 Q. Is there another study? 24 A. There are other mesh</p>
<p style="text-align: right;">Page 159</p> <p>1 Q. To the best of your 2 understanding, is there any published 3 literature which describes mesh 4 contraction like that -- I'm sorry. 5 That's poorly phrased. 6 To the best of your 7 understanding, is there any published 8 medical literature which, when describing 9 this phenomena of contraction, describes 10 something like what Dr. Heit saw at 11 surgery? 12 A. Yes. 13 Q. Okay. Do you know any 14 studies, off the top of your head? 15 A. Yes. 16 Q. Tell me one or two of them. 17 A. There's a study performed 18 by -- Velemir is the first author. 19 Q. You're going to have to 20 spell that for our court reporter. 21 MR. SLATER: V-E-L-E-M-I-R. 22 THE WITNESS: And Jacquetin 23 is the last author. 24 J-A-C-Q-U-E-T-I-N.</p>	<p style="text-align: right;">Page 161</p> <p>1 studies -- I'm sorry -- other ultrasound 2 studies that show mesh contraction. 3 Another one is by Tunn, T-U-N-N. 4 Q. Okay. Were there any 5 ultrasounds even ordered of Mrs. Hammons 6 between Dr. Baker's procedure in 2009 and 7 today, ultrasounds of her pelvis? 8 A. And the first date was? 9 Q. Dr. Baker's procedure in May 10 of 2009. 11 A. She had a pelvic ultrasound 12 in that time, yes. 13 Q. Okay. Do you know when that 14 was? 15 A. It was ordered by 16 Dr. Lackey, I believe. 17 Q. Did it show bunched mesh or 18 any abnormality with the Prolift mesh? 19 A. The indication was not 20 specifically looking at the mesh. What 21 I've been describing to you is those are 22 research findings. Ultrasound to 23 demonstrate mesh, that was not the 24 clinical indication given for the</p>

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<p style="text-align: right;">Page 162</p> <p>1 ultrasound that was performed at that 2 time. 3 Q. Why do you rule out vaginal 4 atrophy and vaginal shortening as causes 5 of Mrs. Hammons' dyspareunia? 6 MR. SLATER: Objection. 7 Compound. Confusing. Lack of 8 foundation. 9 THE WITNESS: I don't 10 believe I did that, to rule those 11 diagnoses out. 12 BY MR. MORIARTY: 13 Q. Well, I asked you for your 14 differential diagnosis of her dyspareunia 15 in July of 2009. Okay. And when you 16 gave it to me, I assumed that -- let me 17 back up. 18 The differential diagnosis 19 that you gave me for her complaints of 20 dyspareunia were hysterectomy scar, 21 anterior mesh, either infected or 22 contracting, or a pelvic infection. 23 Okay. So let me circle back and ask you. 24 Wouldn't vaginal atrophy and</p>	<p style="text-align: right;">Page 164</p> <p>1 Q. Of Mrs. Hammons in 2009. 2 A. So we're talking 3 specifically at the 12-week visit with 4 Dr. Baker? 5 Q. In July of 2009. 6 A. Okay. 7 Q. I'm just asking if atrophy 8 and a shortened vagina are at least in 9 the differential diagnosis. 10 A. In general terms. In his 11 examination, he described the pain 12 specifically at the back cuff where the 13 body of the Prolift and the deep arms are 14 located. 15 Q. Okay. After Dr. Lackey's 16 surgery in December of 2009, would 17 atrophy and a shortened vagina be in the 18 differential diagnosis for Mrs. Hammons' 19 complaints of dyspareunia? 20 A. Those would be potentially 21 in the differential, yes. 22 Q. All right. And how do you 23 rule them out? 24 I'm sorry. Do you rule them</p>
<p style="text-align: right;">Page 163</p> <p>1 a foreshortened vagina be in the 2 differential diagnosis? 3 MR. SLATER: Objection. 4 Lack of foundation. 5 THE WITNESS: Her physical 6 findings at the time of Dr. Heit's 7 examination show specifically 8 where the pain is in the anterior 9 vagina. If the vaginal atrophy 10 were a small contributing factor, 11 then you would expect that to be 12 relieved by the appropriate use of 13 estrogen. 14 And, in fact, she had been 15 using estrogen. And that wasn't 16 sufficient to relieve her 17 dyspareunia. 18 BY MR. MORIARTY: 19 Q. Okay. Let me -- let me ask 20 you this. 21 Are atrophy and a shortened 22 vagina at least in the differential 23 diagnosis? 24 A. Of anyone?</p>	<p style="text-align: right;">Page 165</p> <p>1 out as part of the differential 2 diagnosis? 3 A. It depends on the 4 examination at that point and if the 5 findings point to those features of 6 atrophy or foreshortening as a potential 7 component of her dyspareunia. And when 8 Dr. -- after he did what he felt he could 9 do for her to help her, he decided to 10 send her to a specialist, the kind of 11 person who was taking care of these mesh 12 complications day in and day out. And 13 that's when he found the tense, tender, 14 taut, anterior vagina where the anterior 15 Prolift had been placed. 16 Q. Okay. From whatever 17 descriptions Dr. Lackey had in his 18 records or in his deposition about 19 Mrs. Hammons' complaints of dyspareunia, 20 whenever she made them after December of 21 2009 and before he referred her to 22 Dr. Heit, okay, would atrophy and a 23 shortened vagina be in the differential 24 diagnosis for Mrs. Hammons?</p>

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<p style="text-align: right;">Page 166</p> <p>1 A. They would be in the 2 differential, yes. 3 Q. Okay. And do you have an 4 opinion, to a probability, just based on 5 Dr. Lackey's records and deposition 6 testimony, whether that should be ruled 7 out as a cause of Mrs. Hammons' 8 complaints of dyspareunia? 9 A. It should be evaluated. I 10 don't recall off the top of my head, from 11 the office visits that she had, whether 12 he described atrophy at those visits. 13 Q. From your understanding of 14 the medical records, did Mrs. Hammons use 15 the estrogen cream that she was 16 prescribed as it was prescribed? 17 A. I'm sorry. I don't remember 18 that off the top of my head. 19 MR. MORIARTY: I'm happy to 20 keep going. But if you all want 21 to get your sandwiches and eat, 22 you're more than welcome to do 23 that. And if Dr. Weber wants to 24 take a few-minute break to get</p>	<p style="text-align: right;">Page 168</p> <p>1 hiatus of a year or more since he had 2 last seen her; is that right? 3 A. Yes. 4 Q. Now, one of the complaints 5 and one of the physical findings at that 6 point was a recurrence of her prolapse, 7 correct? 8 A. Yes. 9 Q. And the recurrence was a 10 rectocele; is that right? 11 A. Yes. 12 Q. In other words, whatever 13 native tissue repair Dr. Lackey performed 14 in December of 2009 was not successful 15 beyond at least January of 2012, correct? 16 A. Yes. 17 Q. All right. In other words, 18 it's a recurrence of her posterior 19 prolapse? 20 A. Yes. 21 Q. Some doctors would call it a 22 failure of the first procedure; is that 23 right? 24 A. A failure of the procedure</p>
<p style="text-align: right;">Page 167</p> <p>1 something to eat, that's fine, 2 too. 3 (Brief interruption.) 4 BY MR. MORIARTY: 5 Q. Okay. Doctor, these are the 6 two pages that have the notes for that 7 visit. 8 A. Okay. Thank you. 9 Q. Got it? Why don't you just 10 quickly look at the bottom and the typed 11 notes on the second page. 12 A. Okay. 13 Q. Doctor, while we're after 14 the lunch break, I started by going to 15 January 9, 2012. And I just want to 16 quickly repeat the lead-in, because there 17 was a computer glitch with the court 18 reporter. Okay? 19 A. Yes. 20 Q. All right. So Mrs. Hammons 21 returns to Dr. Lackey January 9, 2012, 22 correct? 23 A. Yes. 24 Q. And this is after some</p>	<p style="text-align: right;">Page 169</p> <p>1 that Dr. Lackey performed? 2 Q. Yes. 3 A. Yes. 4 Q. Okay. In that same visit, 5 she's complaining of dyspareunia, is she 6 not? 7 A. Actually, that's apareunia. 8 The inability to have intercourse at all, 9 apareunia. 10 Q. All right. So she had 11 dyspareunia to the point where they 12 stopped trying? 13 A. Yes. 14 Q. In Dr. Lackey's physical 15 examination, does he note atrophy? 16 A. Yes. 17 Q. Does he describe it in any 18 more detail than that? 19 A. No. 20 Q. Would the differential 21 diagnosis for her dyspareunia and 22 apareunia include atrophy, the rectocele 23 surgery from 2009, the vaginal 24 hysterectomy and Prolift procedure from</p>

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<p style="text-align: right;">Page 170</p> <p>1 May of 2009, at least those things?</p> <p>2 A. I think, if I understand</p> <p>3 your question correctly, the anterior</p> <p>4 Prolift and hysterectomy are joined by an</p> <p>5 "and."</p> <p>6 Q. Well, it was a combined</p> <p>7 procedure, correct?</p> <p>8 A. Correct. So in that case,</p> <p>9 yes.</p> <p>10 Q. All right. I believe on</p> <p>11 August 3rd, 2012, Dr. Rohrer mentioned</p> <p>12 something in his notes about a surgeon</p> <p>13 puncturing the bladder prior to that</p> <p>14 time. Did you see that in the notes when</p> <p>15 you reviewed them?</p> <p>16 A. I did.</p> <p>17 Q. And that's a mistake, is it</p> <p>18 not?</p> <p>19 A. I believe so, based on the</p> <p>20 operative report. That was not recorded.</p> <p>21 Q. All right. Was Mrs. Hammons</p> <p>22 having overactive bladder symptoms in the</p> <p>23 summer of 2012, either based on notes by</p> <p>24 Dr. Lackey or Dr. Rohrer?</p>	<p style="text-align: right;">Page 172</p> <p>1 A. Urethral instability,</p> <p>2 overflow incontinence, stress</p> <p>3 incontinence, fistula, ectopic ureter,</p> <p>4 restrictive bladder disease, which has a</p> <p>5 number of causes. I think those are the</p> <p>6 main ones. Oh, excuse me. Urinary tract</p> <p>7 infection.</p> <p>8 Q. Eventually, Dr. Heit finds</p> <p>9 mesh bunched in the midline, does he not?</p> <p>10 A. Yes.</p> <p>11 Q. All right. Other than</p> <p>12 contraction, what are the possible causes</p> <p>13 of that finding?</p> <p>14 A. In general terms, not</p> <p>15 specific to Mrs. Hammons, it could be</p> <p>16 implantation technique. It could be</p> <p>17 something -- some external influence like</p> <p>18 radiation therapy that would have an even</p> <p>19 more pronounced scarring effect,</p> <p>20 particularly -- well, let's just go</p> <p>21 there. Let's just stop there. Those are</p> <p>22 the main ones that I can think of.</p> <p>23 Q. So several times in your</p> <p>24 report in this case, you refer to</p>
<p style="text-align: right;">Page 171</p> <p>1 A. Now, overactive bladder</p> <p>2 typically refers to the constellation of</p> <p>3 urgency, frequency, and urge</p> <p>4 incontinence. What she was describing</p> <p>5 when she saw Dr. Lackey on August 14th</p> <p>6 was leaking urine without any warning.</p> <p>7 Q. And you're talking about</p> <p>8 2012, correct?</p> <p>9 A. Yes. So that's not -- that</p> <p>10 brief description is not really</p> <p>11 consistent with urge incontinence.</p> <p>12 That's typically labeled under the rubric</p> <p>13 of overactive bladder.</p> <p>14 Q. I'm sorry. I didn't</p> <p>15 understand that. I thought you were</p> <p>16 saying it wasn't overactive bladder. Are</p> <p>17 you saying it is?</p> <p>18 A. No, no. Leaking without</p> <p>19 warning, without an overwhelming sense of</p> <p>20 urgency, that is not OAB.</p> <p>21 Q. So she has that complaint</p> <p>22 that she's leaking without the sense of</p> <p>23 urgency. What's your differential</p> <p>24 diagnosis of that problem at that point?</p>	<p style="text-align: right;">Page 173</p> <p>1 Dr. Heit mentioned that he thought it was</p> <p>2 a surgical technique issue. Do you</p> <p>3 disagree with him?</p> <p>4 A. I disagree to the extent</p> <p>5 that his findings are the worse</p> <p>6 representation of mesh contraction. And</p> <p>7 when she had been examined earlier in</p> <p>8 time, less severe manifestations of the</p> <p>9 mesh contraction existed. From surgical</p> <p>10 videos, et cetera, we know that the</p> <p>11 Prolift mesh often doesn't go in flat.</p> <p>12 It's crumpled, roping, pore collapse.</p> <p>13 And at that point, that's</p> <p>14 not something that can be visualized by</p> <p>15 the surgeon after the vaginal epithelium</p> <p>16 has been closed.</p> <p>17 Q. Okay. Maybe I didn't ask a</p> <p>18 very good question.</p> <p>19 Dr. Heit, in his -- in at</p> <p>20 least his deposition, said that he</p> <p>21 thought it was a technique error by</p> <p>22 Dr. Baker, the implant. Do you disagree</p> <p>23 with Dr. Heit?</p> <p>24 A. I believe what Dr. Heit was</p>

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<p style="text-align: right;">Page 174</p> <p>1 explaining in his deposition testimony 2 was, as if the bunching and crumpling, 3 had it existed to the extent it was when 4 he first saw her all along the way, but 5 with the benefit of the longitudinal 6 records that we have, we can see that, at 7 least to the extent when Dr. Baker saw 8 her at 12 weeks and he was palpating the 9 vaginal apex where the deep arms of the 10 anterior Prolift mesh go and the deep 11 aspect of the body of the Prolift mesh, 12 by his recorded exam, the mesh did extend 13 from the vaginal apex to the location 14 under the bladder base. 15 So to the extent that that 16 represents the coverage that the body of 17 the Prolift mesh is supposed to account 18 for, that didn't -- later in time then, 19 as the contraction progressed, Dr. Heit 20 had his findings. 21 So that in -- if there was 22 folding or clumping, we know there's 23 floor collapse, it would be of a 24 relatively less degree when Dr. Baker saw</p>	<p style="text-align: right;">Page 176</p> <p>1 Q. Okay. Do we know what that 2 "some" is, in a percentage? 3 A. I can give you examples from 4 the literature. 5 Q. No, that's okay. 6 All right. So Scenario 2. 7 If Dr. Baker puts in the mesh and he 8 doesn't lay it completely flat and 9 contraction occurs, could it accentuate 10 the -- whatever fold there was at the 11 time of the implant? 12 A. I'm sorry. Now you've lost 13 me. Can you repeat or rephrase? 14 Q. I asked, do you disagree 15 with Dr. Heit that this configuration he 16 found was a technique error by Dr. Baker. 17 And I think what you're saying is that -- 18 I think what you're saying -- and please 19 correct me if I'm wrong -- is that 20 Dr. Baker could have put it in wrong to 21 some degree, but not the degree that 22 Dr. Heit found it in 2012. 23 Is that what you're saying? 24 MR. SLATER: Objection. You</p>
<p style="text-align: right;">Page 175</p> <p>1 her at 12 weeks, because he documented 2 that the mesh extended from the apex 3 proximally, versus what Dr. Heit found, 4 which was the concentration of the 5 clumping mesh below the bladder base and 6 the urethra and closer to the outside. 7 Q. Okay. I'm not fully 8 understanding your answer. So let me try 9 to follow up. 10 I assume, based on what I 11 know of your beliefs about mesh 12 contraction, that if Dr. Baker put the 13 mesh in perfectly flat, the way it was 14 designed to be put in, there could be 15 contraction that causes a patient 16 problems, correct? 17 MR. SLATER: Objection. 18 Lack of foundation. 19 THE WITNESS: There will be 20 contraction, because mesh 21 contracts under all circumstances 22 in all women. In some women, it 23 will cause them complications. 24 BY MR. MORIARTY:</p>	<p style="text-align: right;">Page 177</p> <p>1 can answer. 2 THE WITNESS: I think we're 3 getting there. 4 When Dr. Baker examined 5 Mrs. Hammons at 12 weeks 6 postoperatively, the main location 7 of mesh contraction that he could 8 identify was at the apex, which 9 are the deep anterior arms of the 10 Prolift. And then based on her 11 subsequent findings, ultimately 12 ending up with Dr. Heit, that mesh 13 contraction continued to occur in 14 a direction, if you will, that 15 sort of drags the vagina closer to 16 the vaginal opening, such that he 17 found it in that bunched and 18 rolled and crumpled position. 19 BY MR. MORIARTY: 20 Q. Okay. So, now if I 21 understand what you're saying, you have 22 no opinion on whether Baker put it in, in 23 some degree, wrong. But if he did, the 24 contraction made that error substantially</p>

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<p style="text-align: right;">Page 178</p> <p>1 worse --</p> <p>2 MR. SLATER: Objection.</p> <p>3 BY MR. MORIARTY:</p> <p>4 Q. -- for the patient?</p> <p>5 Is that what you're saying?</p> <p>6 MR. SLATER: Objection.</p> <p>7 Lack of foundation,</p> <p>8 mischaracterization.</p> <p>9 THE WITNESS: I can try</p> <p>10 again. This is a progressive</p> <p>11 process.</p> <p>12 BY MR. MORIARTY:</p> <p>13 Q. I understand. I'm just</p> <p>14 trying to find out if you disagree with</p> <p>15 Dr. Heit that it was a technique error.</p> <p>16 MR. SLATER: Just that</p> <p>17 question.</p> <p>18 THE WITNESS: Just that</p> <p>19 question. I disagree with</p> <p>20 Dr. Heit.</p> <p>21 BY MR. MORIARTY:</p> <p>22 Q. Okay. Is it your opinion</p> <p>23 that the condition in which Dr. Heit</p> <p>24 found the mesh, when he operated in 2012,</p>	<p style="text-align: right;">Page 180</p> <p>1 but that's my paraphrasing to put it into</p> <p>2 a complete sentence.</p> <p>3 Q. Okay. Where in Dr. Heit's</p> <p>4 November 28, 2012, operative note, if you</p> <p>5 recall, does it describe the treatment of</p> <p>6 a vaginal exposure?</p> <p>7 A. Could I have his operative</p> <p>8 note?</p> <p>9 Q. It's in this stack here.</p> <p>10 It's Exhibit 15. Right there.</p> <p>11 A. So, in the findings, this is</p> <p>12 on the first page towards the bottom, the</p> <p>13 last sentence in the findings, "There's</p> <p>14 also communication with the vaginal</p> <p>15 mucosa through a sinus tract formation."</p> <p>16 Then in the body of the</p> <p>17 operative report -- the body of the</p> <p>18 operative report does not describe the</p> <p>19 specific step in the procedure in which</p> <p>20 he managed the sinus tract formation.</p> <p>21 Q. Okay. And when it says in</p> <p>22 the findings section on the first page of</p> <p>23 Exhibit 15, "There was also communication</p> <p>24 with the vaginal mucosa through a sinus</p>
<p style="text-align: right;">Page 179</p> <p>1 is solely related to contraction?</p> <p>2 A. Well, it's a whole spectrum.</p> <p>3 There's the mesh contraction, the rigid</p> <p>4 scar plating, the bridging fibrosis. All</p> <p>5 of those things happen in concert with</p> <p>6 the mesh contraction that leads to</p> <p>7 pathology findings like the rubbery,</p> <p>8 firm. Not a little thin layer of tissue</p> <p>9 ingrowth as claimed in the IFU.</p> <p>10 Q. Okay. At the November 8,</p> <p>11 2012, office visit, does Dr. Heit</p> <p>12 describe a mesh erosion in the vagina?</p> <p>13 A. November 8th? I have</p> <p>14 November 6th. Is the 8th correct?</p> <p>15 Q. I may have written it down</p> <p>16 wrong.</p> <p>17 He has a November office</p> <p>18 visit. Did he describe a mesh erosion in</p> <p>19 the vagina?</p> <p>20 A. The sentence I have in my</p> <p>21 report is "Vaginal mesh erosion was again</p> <p>22 seen, with odorous vaginal secretions."</p> <p>23 So that's not a direct quote</p> <p>24 lifted from his records word for word,</p>	<p style="text-align: right;">Page 181</p> <p>1 tract formation," does that mean to you</p> <p>2 that there was an erosion in the vaginal</p> <p>3 mucosa of mesh?</p> <p>4 A. The way I interpret that is,</p> <p>5 there's been an interruption of the</p> <p>6 continuity of the vaginal epithelium.</p> <p>7 And within that disruption, there's a</p> <p>8 little tunnel. That's the sinus tract,</p> <p>9 that has epithelium on it, but it</p> <p>10 connects directly to the mesh so that</p> <p>11 there's an area of the mesh that is not</p> <p>12 fully covered by the vagina.</p> <p>13 Q. Okay. But there's no</p> <p>14 description of size in this operative</p> <p>15 note?</p> <p>16 A. That's correct.</p> <p>17 Q. And in that procedure, did</p> <p>18 Dr. -- Dr. Heit use a biologic mesh?</p> <p>19 A. Not a mesh. That term would</p> <p>20 be a "graft."</p> <p>21 Q. Okay. Biologic graft?</p> <p>22 A. Biologic graft.</p> <p>23 Q. And do biologic grafts have</p> <p>24 the potential to erode?</p>

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<p style="text-align: right;">Page 182</p> <p>1 A. Yes.</p> <p>2 Q. Have you ever spoken with</p> <p>3 Dr. Zipper?</p> <p>4 A. No.</p> <p>5 Q. Ever met him?</p> <p>6 A. No.</p> <p>7 Q. Have you seen any record in</p> <p>8 this -- any record of Mrs. Hammons in</p> <p>9 this case diagnosing a neuronal</p> <p>10 entrapment?</p> <p>11 A. In her clinical care, is</p> <p>12 that what you're referring to? In her</p> <p>13 medical records?</p> <p>14 Q. Yes.</p> <p>15 A. Yes, okay. Then the answer</p> <p>16 is no.</p> <p>17 Q. Okay. Are there studies</p> <p>18 available to diagnose whether there's</p> <p>19 such a thing as neuronal entrapment in a</p> <p>20 patient?</p> <p>21 A. Yes.</p> <p>22 Q. And what kind of study is</p> <p>23 that?</p> <p>24 A. Those are primarily based</p>	<p style="text-align: right;">Page 184</p> <p>1 findings nerves entrapped in mesh that</p> <p>2 leads to the diagnosis of neuronal</p> <p>3 entrapment.</p> <p>4 So it's a clinical diagnosis</p> <p>5 for doctors caring for patients in the</p> <p>6 office. It's been substantiated by</p> <p>7 research, as I just described to you.</p> <p>8 Q. Is that process that you're</p> <p>9 describing part of a foreign body</p> <p>10 reaction?</p> <p>11 A. Yes. The foreign body</p> <p>12 reaction, inflammatory reaction, which</p> <p>13 worsens -- the higher the mesh burden,</p> <p>14 the worse the foreign body reaction and</p> <p>15 inflammatory reaction. So definitely,</p> <p>16 yes, it would also be directly related to</p> <p>17 the neuronal entrapment.</p> <p>18 Q. Have you ever published on</p> <p>19 foreign body reactions?</p> <p>20 A. No.</p> <p>21 Q. Okay. Are there -- what</p> <p>22 tests can be run on a patient to see if</p> <p>23 they have reduced bladder compliance?</p> <p>24 A. You could do urodynamic</p>
<p style="text-align: right;">Page 183</p> <p>1 out of the hernia mesh literature where,</p> <p>2 in the shrinkage and contraction that</p> <p>3 occurs with hernia mesh, the neurons that</p> <p>4 supply different sensations to the skin,</p> <p>5 of pain, heat, pressure, become entrapped</p> <p>6 and cause symptoms, primarily pain.</p> <p>7 Q. No. I'm asking, is there a</p> <p>8 test that you as a doctor could order to</p> <p>9 diagnose neuronal entrapment?</p> <p>10 A. No. That's a clinical</p> <p>11 decision -- a clinical diagnosis. Pardon</p> <p>12 me.</p> <p>13 Q. Okay. And when you say</p> <p>14 clinical diagnosis, that's a physician's</p> <p>15 judgment kind of diagnosis using all the</p> <p>16 clues that you can gather from a physical</p> <p>17 exam and a history, right? Is that</p> <p>18 right?</p> <p>19 A. A physical exam and history</p> <p>20 on that patient, in addition to the</p> <p>21 studies. You're not necessarily taking a</p> <p>22 tissue sample from this patient. But</p> <p>23 there are plenty of clinical studies in</p> <p>24 which tissue samples have been processed</p>	<p style="text-align: right;">Page 185</p> <p>1 testing in which the bladder is</p> <p>2 backfilled with fluid. You could also</p> <p>3 have the patient go home with a measuring</p> <p>4 device and have her measure voids over a</p> <p>5 short period of time, like 24 hours, and</p> <p>6 see what her volumes voided are.</p> <p>7 There are also pressure</p> <p>8 studies -- that's part of the</p> <p>9 urodynamics -- where you're not only</p> <p>10 looking at the volume instilled, but also</p> <p>11 the pressure increase as the volume is</p> <p>12 being instilled.</p> <p>13 Q. Has -- to the best of your</p> <p>14 knowledge, has Mrs. Hammons undergone any</p> <p>15 of those studies in 2015?</p> <p>16 A. Not in 2015, no.</p> <p>17 Q. Are you going to render any</p> <p>18 opinions in this case about Mrs. Hammons'</p> <p>19 restriction on lifting at her job?</p> <p>20 MR. SLATER: Objection.</p> <p>21 Depends on the question that's</p> <p>22 being asked.</p> <p>23 THE WITNESS: I wasn't aware</p> <p>24 that she had restrictions on</p>

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<p style="text-align: right;">Page 186</p> <p>1 lifting related to her job. 2 BY MR. MORIARTY: 3 Q. Okay. Do you know anything 4 about who put on any particular 5 restrictions that she's under or when 6 those restrictions were placed? 7 A. No, I don't. 8 Q. Okay. In your opinion, to a 9 probability, has Mrs. Hammons' smoking 10 had any effect on the health of her 11 tissues? 12 A. No, I don't believe so. 13 She's evidenced normal healing throughout 14 her course if her -- in her gynecologic 15 surgeries and also others. 16 Q. So even though it's 17 considered to be a risk factor for 18 someone like Mrs. Hammons, in your 19 opinion it was not a factor at all in her 20 development of prolapse originally or the 21 recurrence of her posterior prolapse? 22 A. Correct. 23 Q. And is that just based on 24 the fact that she seemed to heal well</p>	<p style="text-align: right;">Page 188</p> <p>1 A. Yes. 2 Q. All right. I have a couple 3 of questions about that. First of all, 4 do you know whether Dr. Heit submitted 5 100 percent of the mesh that he removed 6 to the pathology department? 7 A. I'd have to refer to his 8 operative report. 9 Q. Well, they're here. Here's 10 the first one right there. So right now 11 you are looking at Exhibit 15, is it? 12 A. Yes, 15. On the second page 13 of the operative note toward the bottom 14 of the description of procedures, "The 15 right portion of the mesh was excised by 16 cutting its insertion points into the 17 obturator internus muscle with curved, 18 heavy Mayo scissors. Sent to pathology 19 for evaluation." 20 Q. Okay. So are you assuming 21 that he sent 100 percent of what he 22 removed? 23 A. That's what it sounds like. 24 And then on the left side, he describes a</p>
<p style="text-align: right;">Page 187</p> <p>1 after her surgeries in 2009 and 2012 and 2 2013? 3 A. And 2014, I believe, is when 4 she had a knee replacement. Yeah. 5 I've never seen any healing 6 impairment in her at all. 7 Q. All right. Well, could she 8 have a chronic impact on tissues without 9 having acute healing issues 10 postoperatively? 11 A. That's possible. I don't 12 think that's been demonstrated in the 13 literature. 14 Q. At Page 8 of your report, 15 Exhibit 1, you're talking about 16 Dr. Heit's two procedures, and you went 17 back to the pathology reports and you 18 were doing some calculations about how 19 much mesh was there compared with the 20 total mesh that may have been implanted, 21 correct? 22 A. Yeah. 23 Q. Do you see those 24 measurements?</p>	<p style="text-align: right;">Page 189</p> <p>1 similar dissection and removal of the 2 mesh. He doesn't specifically state 3 again that the specimen was sent to 4 pathology, but since pathology received 5 two specimens -- and I think, on the 6 pathology report, they were identified as 7 right and left, if I'm not mistaken. 8 So without the specific 9 words saying he sent the left, I would 10 assume that to be the case. 11 Q. Okay. And do you know 12 whether the pathologist just measured the 13 specimen as submitted or whether they 14 tried to flatten out the mesh, if you 15 will? 16 A. I have no idea. 17 Q. All right. Do you have an 18 opinion, to a reasonable degree of 19 medical probability, as to how much mesh 20 remains in Patricia Hammons? 21 A. Well, clearly, she has the 22 entirety of the four mesh arms. And it's 23 possible that she also has a component of 24 the mesh body leading up to the arms and</p>

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<p style="text-align: right;">Page 190</p> <p>1 existing lateral -- in a lateral 2 position. 3 Q. Have you ever done a 4 calculation of what you believe is that 5 amount of mesh? 6 A. Remaining in her? 7 Q. Yes. 8 A. No. 9 Q. In your report, you stated 10 that it's your opinion that the mesh will 11 continue to cause inflammation and 12 continue to contract; is that right? 13 A. Yes. 14 Q. What's the basis for that 15 opinion? 16 A. The basis for that opinion 17 is the fact that the body's response to a 18 foreign body doesn't ever go away. It's 19 not transient. It continues for as long 20 as the foreign body -- in this case, the 21 mesh -- is in place. And we know that 22 the higher the level of inflammatory 23 reaction you have incites an even greater 24 degree of mesh contraction.</p>	<p style="text-align: right;">Page 192</p> <p>1 are not recurrences caused by Prolift, 2 are they? 3 A. Now, in general, what we 4 know from the literature is that when 5 mesh is used, Prolift mesh is used in one 6 compartment, that that can deflect the 7 forces of intra-abdominal pressure and 8 have that force impact more fully on the 9 compartment that had not previously been 10 treated with the Prolift mesh. 11 Q. I thought I asked earlier 12 whether the rectocele and enterocele that 13 Dr. Lackey found in the fall of 2009 were 14 related to Prolift. And you said no. I 15 thought I asked that. 16 MR. SLATER: Could you read 17 that back. 18 (Whereupon, the court 19 reporter read back the requested 20 portion of testimony.) 21 MR. SLATER: Objection. 22 Foundation, argumentive. 23 THE WITNESS: Perhaps I 24 misunderstood the question.</p>
<p style="text-align: right;">Page 191</p> <p>1 So there's plenty of 2 evidence about how mesh behaves in use, 3 in the body, to support that opinion. 4 Q. Have you seen any evidence 5 from the medical records themselves that 6 Mrs. Hammons has had chronic bladder or 7 vaginal infections? 8 A. No, I don't believe so. 9 Q. What about chronic urinary 10 tract infections? 11 A. Oh, I'm sorry. I thought 12 that was part of the question that you 13 just asked. But in any event, no. No. 14 Q. I don't recall right now. 15 Did you see the office records of 16 Dr. Thorn, the orthopedic surgeon who 17 performed the knee replacement surgery? 18 A. I'd have to look at my 19 reliance list. I believe so, but I would 20 know better to look at the list. 21 Q. If Mrs. Hammons claims 22 that -- I'm sorry. Let me rephrase that. 23 If Mrs. Hammons currently 24 has a rectocele or an enterocele, those</p>	<p style="text-align: right;">Page 193</p> <p>1 BY MR. MORIARTY: 2 Q. Okay. Well, let's -- let me 3 ask it this way. Is it your 4 understanding that Mrs. Hammons currently 5 has a rectocele and/or enterocele? 6 A. Give me a minute. Yes. 7 Q. And are you attributing her 8 current rectocele and enterocele to 9 Prolift, the Prolift surgery she had in 10 May of 2009? 11 A. In general, we know that her 12 risk is higher. If that's exactly why 13 her rectocele developed, I can't say that 14 with 100 percent certainty. 15 Q. Are you going to render an 16 opinion, to a reasonable probability, 17 that that's what happened? 18 A. Yes, I think it's more 19 likely than not that the Prolift would 20 have had a role in that. 21 Q. If Dr. Baker had performed a 22 vaginal hysterectomy and an anterior 23 colporrhaphy in May of 2009, doesn't that 24 native tissue repair similarly deflect</p>

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<p style="text-align: right;">Page 194</p> <p>1 forces to the untreated compartment?</p> <p>2 A. It can. What happens</p> <p>3 when -- the difference between a native</p> <p>4 repair like an anterior colporrhaphy is</p> <p>5 that that's closer to what the outcome</p> <p>6 is. It's not a stage zero. What we've</p> <p>7 learned over time is that getting women</p> <p>8 like Mrs. Hammons to a point where they</p> <p>9 are at stage zero, that's not necessarily</p> <p>10 the best outcome for them. And,</p> <p>11 certainly, with regard to the Prolift,</p> <p>12 there are a lot of reasons why, in</p> <p>13 addition to the prolapse issue.</p> <p>14 So that in an anterior</p> <p>15 repair, to a lesser extent the forces</p> <p>16 could affect the posterior wall.</p> <p>17 Q. Let me make sure I</p> <p>18 understand what you're saying.</p> <p>19 Mrs. Hammons had a pelvic floor disorder,</p> <p>20 did she not?</p> <p>21 A. Yes.</p> <p>22 Q. And she was at risk for</p> <p>23 that, correct?</p> <p>24 A. Yes. She developed it.</p>	<p style="text-align: right;">Page 196</p> <p>1 BY MR. MORIARTY:</p> <p>2 Q. -- is that right?</p> <p>3 A. No, I wouldn't agree with</p> <p>4 that. She didn't have any evidence of a</p> <p>5 posterior pelvic disorder, if you want to</p> <p>6 call it that.</p> <p>7 Unmasking means something is</p> <p>8 in place and you just happened to find it</p> <p>9 later, as opposed to something that's not</p> <p>10 there and develops subsequently.</p> <p>11 Q. Is it likely -- is it more</p> <p>12 likely than not, that regardless of the</p> <p>13 surgical technique chosen by Dr. Baker in</p> <p>14 May of 2009, that Mrs. Hammons at some</p> <p>15 point would have developed a rectocele</p> <p>16 and enterocele?</p> <p>17 A. No. I can't say it's more</p> <p>18 likely that she would. She is at risk.</p> <p>19 But I -- I wouldn't say that it's more</p> <p>20 than likely that she definitely would.</p> <p>21 Q. Do you have any way to know,</p> <p>22 Dr. Weber, the degree to which</p> <p>23 Mrs. Hammons' vagina was shortened by</p> <p>24 Prolift versus her vaginal hysterectomy</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. Okay. And the first</p> <p>2 manifestation of it was a cystocele,</p> <p>3 correct, and an apical prolapse?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And the posterior</p> <p>6 prolapse, the rectocele and enterocele,</p> <p>7 manifested later, correct?</p> <p>8 A. Yes.</p> <p>9 Q. After her first repair</p> <p>10 surgery, correct?</p> <p>11 A. Yes.</p> <p>12 Q. All right. It's not the</p> <p>13 mesh that actually creates a rectocele.</p> <p>14 It just deflects forces in the direction</p> <p>15 of the posterior compartment; is that</p> <p>16 correct?</p> <p>17 A. That's the explanation or</p> <p>18 the rationale given for this research</p> <p>19 finding, yes.</p> <p>20 Q. All right. And so, in some</p> <p>21 sense, it unmasks a part of the body</p> <p>22 that's already diseased --</p> <p>23 MR. SLATER: Objection to</p> <p>24 that term "unmasked."</p>	<p style="text-align: right;">Page 197</p> <p>1 and her posterior procedures done by</p> <p>2 Dr. Lackey?</p> <p>3 A. No, I don't.</p> <p>4 Do you mind if I stop for a</p> <p>5 few minutes and run to the restroom?</p> <p>6 (Short break.)</p> <p>7 BY MR. MORIARTY:</p> <p>8 Q. In your report, you comment</p> <p>9 or mention Dr. Zipper's findings of a</p> <p>10 Grade 3 apical prolapse. Did you see</p> <p>11 that? And a Grade 3 posterior prolapse?</p> <p>12 A. I believe he described those</p> <p>13 as stages. I want to be sure about that.</p> <p>14 Yes. Stage. Correct.</p> <p>15 Q. If she has apical and</p> <p>16 posterior prolapse, those are recurrences</p> <p>17 from the procedure done by Dr. Heit and</p> <p>18 Lackey, correct?</p> <p>19 A. I would agree with that as</p> <p>20 far as -- excuse me -- as far as the</p> <p>21 posterior prolapse. She had apical</p> <p>22 prolapse even before she saw Dr. Baker.</p> <p>23 Q. I understand that. But</p> <p>24 Baker didn't repair it. Lackey didn't</p>

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<p style="text-align: right;">Page 198</p> <p>1 repair it in the fall of '09. The only 2 apical repair was by Dr. Heit in November 3 of 2012, correct? 4 A. Yes. 5 Q. So if Mrs. Hammons now has 6 an apical prolapse, that is a recurrence 7 from his repair; is that true? 8 A. Yes. 9 Q. Was that apical prolapse 10 repair to the native tissue, or was that 11 part of the mesh procedure that he 12 performed? 13 A. The apical suspension 14 procedure was a sacrospinous ligament 15 fixation. And in the operative report, 16 he described providing a connection 17 between the anterior vaginal cuff, the 18 deepest part of the anterior of the 19 vagina, to the sacrospinous ligament 20 sutures, and posteriorly using the 21 biological graft. 22 Q. All right. So if I 23 understand what you just said, he used 24 the biological graft for the posterior</p>	<p style="text-align: right;">Page 200</p> <p>1 saying. Yes. 2 Q. Every time -- I'm sorry. 3 Would you agree with me that 4 every time Mrs. Hammons has one of these 5 procedures from May of 2009 onward, it 6 increases the risks of her having scar 7 tissue and dyspareunia? 8 A. In general terms, yes. 9 Q. Now, I know in at least your 10 primary report you have rendered some 11 opinions about bidirectional elasticity, 12 correct? 13 A. Yes. 14 Q. Is there some aspect of 15 Mrs. Hammons' current complaints which is 16 a result, in your opinion, of mesh not 17 being bidirectionally elastic? 18 MR. SLATER: Objection. 19 Foundation. 20 THE WITNESS: I think that 21 is related to issues of pore 22 collapse and maintaining the 23 intended characteristics of the 24 mesh out of the box and into the</p>
<p style="text-align: right;">Page 199</p> <p>1 repair, but the apical repair was a 2 native tissue repair, correct? 3 A. Yes. 4 Q. So if she now has a 5 Stage III rectocele, that is a failure of 6 the biologic graft that Dr. Heit used in 7 November of 2012, correct? 8 A. Yes. 9 Q. And if she has an apical 10 prolapse, that's a failure of the native 11 tissue repair that he did also in 12 November of 2012, correct? 13 A. Yes. 14 Q. All right. So, for 15 Mrs. Hammons, she's had recurrences now 16 twice in the posterior compartment; is 17 that right? 18 A. She developed posterior 19 vaginal prolapse. Dr. Lackey fixed it. 20 She developed a recurrence, and Dr. Heit 21 fixed it. 22 Q. Right. So she's recurred 23 twice. 24 A. Yes. I see what you're</p>	<p style="text-align: right;">Page 201</p> <p>1 patient. I'll just stop there. 2 BY MR. MORIARTY: 3 Q. All right. Let me make sure 4 I understand. I asked earlier about what 5 you thought Mrs. Hammons' current 6 problems were related to her Prolift. 7 And what she told me back then -- and I 8 told you I would give you more of a 9 chance to talk about it -- dyspareunia 10 leading to apareunia, contraction and 11 vaginal distortion, erosions in the 12 vagina and the bladder, correct? 13 A. Those are the problems that 14 she has experienced and some she 15 continues to experience. 16 Q. Okay. To the best of -- I'm 17 sorry. 18 In your opinion, to a 19 probability, does she continue to 20 experience erosion in the bladder? 21 A. She hasn't been evaluated 22 for that since her last visit with 23 Dr. Heit, so I can't exclude that with -- 24 definitely.</p>

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<p style="text-align: right;">Page 202</p> <p>1 Q. There's no evidence in the 2 medical records from 2013 to now, August 3 2015, that she has further bladder 4 erosion, correct? 5 A. Her worsening frequency and 6 urgency of urination could be a sign of 7 bladder mesh erosion. She hasn't been 8 further evaluated on the basis of those 9 symptoms in the only way that you can 10 diagnose bladder mesh erosion. 11 Q. Okay. I just need to know, 12 and my client needs to know, whether, in 13 your opinion, to a reasonable degree of 14 medical probability, she currently has 15 erosion into the bladder from any mesh. 16 A. Yeah, I can't answer that 17 with a yes or a no. It's possible. The 18 only way to find that out would be for 19 her to have further evaluation. 20 Q. In your opinion, to a 21 probability, is she currently having 22 erosion of mesh into the vagina? 23 A. No, not as of May 5, 2015. 24 Q. In your opinion, to a</p>	<p style="text-align: right;">Page 204</p> <p>1 to further evaluate her situation to get 2 the kind of information that I think 3 you're looking for. 4 Q. As of today, the opinion 5 that you just gave is a clinical 6 diagnosis, in your terms; is that right? 7 A. Yes. 8 Q. Okay. 9 A. Based on how -- what we know 10 about how mesh behaves and everything 11 that Mrs. Hammons has been through. 12 Q. Okay. And are you going to 13 render opinions, to a reasonable degree 14 of medical probability, about any other 15 problems that she will experience in the 16 future as a result of her Prolift? 17 MR. SLATER: When you say 18 "other problems," do you mean are 19 there opinions as to the future? 20 MR. MORIARTY: Yeah. 21 BY MR. MORIARTY: 22 Q. Other medical problems that 23 she -- that Mrs. Hammons is going to 24 experience in the future.</p>
<p style="text-align: right;">Page 203</p> <p>1 probability, what is the current cause of 2 her dyspareunia and/or apareunia? 3 A. I think the causes are 4 related to the presence of the Prolift 5 mesh, even though a certain amount of it 6 has been removed. The scarring and 7 damage to the vaginal tissue on a nerve 8 and blood vessel level that continues to 9 affect her, and to the -- in the areas 10 where the Prolift mesh still exists, the 11 ongoing foreign body reaction and 12 inflammatory process that continues the 13 vicious cycle of scarring, and so on. 14 Q. Are there any objective 15 tests that can be run on Mrs. Hammons to 16 confirm or deny the description that you 17 just gave? 18 A. Imaging can identify the 19 mesh. MRI, ultrasound. 20 An objective test is -- 21 other than linking her symptoms -- her 22 symptoms, the findings on the physical 23 examination, and then possibly the 24 results of imaging, that would be the way</p>	<p style="text-align: right;">Page 205</p> <p>1 A. In -- in addition to the 2 ones that she already has? 3 Q. Well, we've talked about 4 erosions, and now we've talked about 5 dyspareunia and apareunia. And I assume 6 that the contraction and vaginal 7 distortion is, in your opinion, linked to 8 the dyspareunia and apareunia, correct? 9 A. Yes. 10 Q. Okay. So what I need to 11 find out before I leave Philadelphia is 12 whether you intend to go to trial and 13 testify that Mrs. Hammons is likely to 14 experience other physical complaints 15 related to Prolift into the future. 16 A. I think it's more likely 17 than not, she has a substantial mesh 18 burden. She's already, unfortunately, 19 shown herself to be someone who's 20 responding with a severe intensity of the 21 inflammatory reaction and the foreign 22 body reaction and bridging fibrosis and 23 the scar plating. And she has all of 24 those mesh arms in the obturator spaces,</p>

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<p style="text-align: right;">Page 206</p> <p>1 the hip and the groin. I would be very 2 concerned that she would be developing 3 new complications as a result of that. 4 Q. Okay. I understand as a 5 physician and a compassionate person you 6 may be very concerned about that. My 7 question is whether you have an opinion, 8 to a reasonable degree of medical 9 probability, that she is going to develop 10 certain specific problems in the future 11 related to her Prolift. 12 A. Yes. 13 Q. Okay. And what are those 14 problems going to be? 15 A. The problems are likely to 16 be in the areas where she continues to 17 have the mesh, which are the obturator 18 spaces in the groin and all the muscles 19 that the mesh arms have gone through and 20 the reaction that we talked about. And 21 to the extent that there's still mesh 22 left in the vagina, then she would be 23 manifesting that as a vaginal mesh 24 erosion. Even worse, another bladder</p>	<p style="text-align: right;">Page 208</p> <p>1 mesh erosion in the bladder, or some 2 infection of the remaining mesh arms, is 3 more likely than not to happen with 4 Patricia Hammons. 5 A. Yes. I did think I answered 6 that. 7 Q. And what is the basis for 8 your opinion that she is likely to suffer 9 either bladder or vaginal erosion? 10 A. The ongoing mesh burden. 11 The ongoing chronic inflammatory foreign 12 body reaction that's continuing to incite 13 chemicals, cell death, scarring, further 14 nerve damage. Those are all the things 15 that form the basis for that opinion. 16 Q. So is it your opinion that 17 because these are likely to occur, 18 these -- this should all be removed 19 surgically soon to prevent that? 20 A. That's -- 21 MR. SLATER: Objection. 22 Foundation. 23 THE WITNESS: That's a 24 clinical decision that would need</p>
<p style="text-align: right;">Page 207</p> <p>1 mesh erosion. Those would be the 2 locations. 3 Q. Okay. So the only specific 4 medical problems you mentioned were 5 vaginal mesh erosion and bladder erosion. 6 Do you think either of those are likely, 7 based on everything you've reviewed in 8 this case? 9 A. Well, I think you also 10 included in that the mesh -- or at least 11 I did -- the mesh arms. So they are 12 carrying on with their issues. They 13 could be infected. There are many cases 14 in the literature reported of rapidly 15 developing severe infections that occur 16 quite remote from the index mesh 17 implantation. So she remains at risk for 18 that in the groin where those four mesh 19 arms are. 20 Q. Okay. Dr. Weber, I 21 understand that she may be at risk. All 22 kinds of things are possible. What I 23 need to find out is whether you have an 24 opinion that mesh erosion in the vagina,</p>	<p style="text-align: right;">Page 209</p> <p>1 to be made between Mrs. Hammons 2 and her possible explanting 3 surgeon. 4 BY MR. MORIARTY: 5 Q. Okay. To the best of your 6 knowledge, is there any peer-reviewed 7 literature published that would support 8 your opinion that mesh arms in a patient 9 like Mrs. Hammons are likely to be 10 infected long-term? 11 A. Well, as I told you, there 12 are reports in the literature. That's 13 not a number that you can relate to, 14 okay, because of this mesh arm, she has a 15 risk of XY over her lifetime. Those data 16 don't exist. 17 Q. Is there any data to support 18 a mesh infection rate of greater than 19 50 percent? 20 A. That's something that can't 21 be calculated from the literature, as it 22 exists. 23 Q. So there is no literature to 24 support an opinion that mesh arms are</p>

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<p style="text-align: right;">Page 210</p> <p>1 likely to be infected long-term, correct?</p> <p>2 A. I've told you what I know</p> <p>3 about the literature. That's -- you</p> <p>4 don't get a numerator and a denominator.</p> <p>5 I don't have an -- I don't have a figure</p> <p>6 for you, a percentage figure, 50 percent</p> <p>7 or higher. You asked for my opinion, and</p> <p>8 I gave it to you.</p> <p>9 Q. Well, what -- is your</p> <p>10 understanding of more likely than not to</p> <p>11 be greater than 50 percent chance of</p> <p>12 something occurring?</p> <p>13 A. More likely than not.</p> <p>14 Q. Is it greater than</p> <p>15 50 percent chance of occurring, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. So what I'm trying to</p> <p>18 find out is whether there's any published</p> <p>19 literature --</p> <p>20 A. No.</p> <p>21 Q. -- to support a greater than</p> <p>22 50 percent chance that a patient with a</p> <p>23 mesh will be infected.</p> <p>24 A. No. That literature does</p>	<p style="text-align: right;">Page 212</p> <p>1 that literature does not exist.</p> <p>2 Q. Is there any literature</p> <p>3 regarding midurethral slings for stress</p> <p>4 urinary incontinence with infection rates</p> <p>5 of greater than 50 percent?</p> <p>6 A. I have not mastered that</p> <p>7 literature completely.</p> <p>8 Q. Has Mrs. Hammons ever</p> <p>9 complained to a physician, in any of the</p> <p>10 medical records that you have seen, of</p> <p>11 pelvic pain unrelated to sexual</p> <p>12 intercourse?</p> <p>13 A. Not that I can recall right</p> <p>14 now.</p> <p>15 Q. All right. So as I</p> <p>16 understand it from your general primary</p> <p>17 report, you have criticisms of Ethicon</p> <p>18 for the representations they made about</p> <p>19 bidirectional elasticity, correct?</p> <p>20 MR. SLATER: Didn't we go</p> <p>21 over this already? You want to go</p> <p>22 over it again?</p> <p>23 MR. MORIARTY: She didn't</p> <p>24 answer me. That's why I want to</p>
<p style="text-align: right;">Page 211</p> <p>1 not exist.</p> <p>2 Q. Okay. So from all the</p> <p>3 hernia literature, from all the pelvic</p> <p>4 mesh literature, the thousands of</p> <p>5 articles that have been written, there's</p> <p>6 nothing about infection rates greater</p> <p>7 than 50 percent in patients who have mesh</p> <p>8 long-term?</p> <p>9 A. I misunderstood your</p> <p>10 question, then. I thought we were</p> <p>11 talking about prolapse. I didn't realize</p> <p>12 we were talking about hernia. Because</p> <p>13 the most common chronic infection that</p> <p>14 hernia patients have is pain. So pain</p> <p>15 would be another thing that would happen</p> <p>16 with her mesh arms.</p> <p>17 I have not done a complete</p> <p>18 review of the hernia literature to come</p> <p>19 up with a percentage.</p> <p>20 Q. Is there any published</p> <p>21 literature regarding mesh for pelvic</p> <p>22 organ prolapse in which there was an</p> <p>23 infection rate greater than 50 percent?</p> <p>24 A. No. I think I told you,</p>	<p style="text-align: right;">Page 213</p> <p>1 find out what the damages were</p> <p>2 first. So now I'm circling</p> <p>3 back --</p> <p>4 MR. SLATER: I object. The</p> <p>5 question doesn't make sense as</p> <p>6 asked. Lack of foundation,</p> <p>7 mischaracterization.</p> <p>8 MR. MORIARTY: Okay.</p> <p>9 MR. SLATER: It doesn't make</p> <p>10 sense.</p> <p>11 THE WITNESS: Could you</p> <p>12 repeat that?</p> <p>13 BY MR. MORIARTY:</p> <p>14 Q. What's your -- in just a few</p> <p>15 sentences, what is your opinion about</p> <p>16 bidirectional elasticity?</p> <p>17 MR. SLATER: Don't answer</p> <p>18 that question.</p> <p>19 Next question. It's been</p> <p>20 asked in other depositions. She's</p> <p>21 been through it.</p> <p>22 BY MR. MORIARTY:</p> <p>23 Q. So how did Ethicon's</p> <p>24 representations about bidirectional</p>

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<p style="text-align: right;">Page 214</p> <p>1 elasticity harm Patricia Hammons, in your 2 opinion?</p> <p>3 A. Once a claim has been 4 recognized as without foundation, without 5 data, despite the fact that it's been 6 present in IFU after IFU, then I become 7 very concerned that other statements also 8 lack data to support.</p> <p>9 And, in fact, that is also 10 true, that there are claims that Ethicon 11 has made time and time again until 12 finally someone challenges them, like the 13 FDA, and it turns out they have no 14 clinical data to support that. In fact, 15 they're misrepresenting that this is a 16 statement that they can actually support.</p> <p>17 Q. All I want to find out is 18 how Ethicon's claims regarding 19 bidirectional elasticity harmed this 20 specific patient.</p> <p>21 A. Because she believed what 22 Ethicon said. She made a decision to 23 allow this to be implanted in her body 24 based on information that she had been</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. Mrs. Hammons did not?</p> <p>2 A. Mrs. Hammons relied on 3 Dr. Baker's expertise and authority as a 4 physician to follow his recommendations. 5 And the information that he conveyed to 6 her, his misplaced confidence in the 7 Prolift product was what made 8 Mrs. Hammons get the Prolift in the first 9 place.</p> <p>10 Q. Okay. I understand that's 11 your opinion. My question is very 12 simple.</p> <p>13 Did Mrs. Hammons herself 14 rely on anything about bidirectional 15 elasticity when she made the decision --</p> <p>16 A. No.</p> <p>17 Q. -- to have Prolift?</p> <p>18 A. No.</p> <p>19 MR. SLATER: Are you guys 20 withdrawing the intermediary from 21 this case?</p> <p>22 MR. MORIARTY: Is that a 23 rhetorical question?</p> <p>24 MR. SLATER: It's an ironic,</p>
<p style="text-align: right;">Page 215</p> <p>1 given by the company and from her doctor 2 who had been given that information by 3 the company, when the company is known to 4 withhold information, make misleading and 5 inaccurate claims.</p> <p>6 And if Mrs. Hammons had 7 known that Ethicon was doing those kinds 8 of things to information that she 9 received and Dr. Baker knew, as he 10 testified, he would not have offered her 11 the Prolift, and she wouldn't be in the 12 situation that she's in now.</p> <p>13 Q. Is there any evidence that 14 Dr. Baker talked with Mrs. Hammons 15 specifically about bidirectional 16 elasticity?</p> <p>17 A. No, he didn't talk with 18 Mrs. Hammons about that.</p> <p>19 Q. Okay. So Mrs. Hammons 20 didn't rely on statements about 21 bidirectional elasticity in deciding 22 whether to have this procedure or not, 23 correct?</p> <p>24 A. She relied --</p>	<p style="text-align: right;">Page 217</p> <p>1 tired comment. Or a tired, ironic 2 comment. It seemed funnier in my 3 head.</p> <p>4 Susan almost laughed.</p> <p>5 MS. ROBINSON: I almost 6 responded.</p> <p>7 BY MR. MORIARTY:</p> <p>8 Q. And so did Mrs. Hammons have 9 any physical injury because of a 10 characteristic of the mesh, such as that 11 it was not bidirectionally elastic?</p> <p>12 MR. SLATER: Objection. 13 Foundation. Misconstrues the 14 issue.</p> <p>15 THE WITNESS: She may have.</p> <p>16 BY MR. MORIARTY:</p> <p>17 Q. Did she, to a reasonable 18 degree of medical probability, have an 19 injury associated with some 20 characteristic that it was not 21 bidirectionally elastic?</p> <p>22 A. I don't know.</p> <p>23 MR. SLATER: It happened 24 quickly. I object again. Lack of</p>

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<p style="text-align: right;">Page 218</p> <p>1 foundation, misconstrues the 2 issue. 3 BY MR. MORIARTY: 4 Q. There's some discussion in 5 your primary report about pore size, this 6 difference between -- I think it's a 7 millimeter and 75 microns. You're very 8 familiar with that issue, correct? 9 MR. SLATER: Objection. 10 Mischaracterizes. 11 THE WITNESS: Yes. 12 BY MR. MORIARTY: 13 Q. Okay. Can you point to any 14 specific harm caused to Patricia Hammons 15 assuming that the pore size was 16 75 microns instead of one millimeter? 17 MR. SLATER: Objection. 18 Lack of foundation. 19 Mischaracterizes the issue. 20 THE WITNESS: Yes. 21 BY MR. MORIARTY: 22 Q. Okay. Is that a separate 23 opinion from what you've already told me 24 about the foreign body reaction and</p>	<p style="text-align: right;">Page 220</p> <p>1 facts in this case except for one. So 2 Mrs. Hammons, same age, same 3 characteristics, has a vaginal 4 hysterectomy. There's no apical repair. 5 Has a transvaginal mesh placed with the 6 same kind of trocars and equipment. But 7 that mesh has pore sizes or effective 8 pore sizes of one millimeter. 9 Is it your opinion that 10 these things would not have happened to 11 Mrs. Hammons over the course of 2009 and 12 '10? 13 A. It is my opinion that she 14 would not have developed mesh contraction 15 to the extent that she did because of 16 pore collapse and bridging fibrosis and 17 ridged scar plating and all the things 18 that we've been talking about all day. 19 Whether she would have had 20 no complications whatsoever, I can't 21 answer that. 22 Q. Okay. So is it your opinion 23 that with a pore size or an effective 24 pore size of one millimeter, she would</p>
<p style="text-align: right;">Page 219</p> <p>1 contraction? 2 A. No, that's the same issue. 3 Q. Okay. So, in your opinion, 4 if the Prolift inserted in Ms. Hammons 5 had one-millimeter pore sizes, she 6 wouldn't have developed these problems? 7 MR. SLATER: Objection. 8 Foundation. Incomplete question. 9 Incomplete hypothetical. 10 Misconstrues the issue. 11 BY MR. MORIARTY: 12 Q. Is that your opinion? 13 MR. SLATER: You can answer. 14 THE WITNESS: Effective pore 15 size and -- and I can't predict 16 what would happen with a specific 17 patient. Effective pore size 18 greater than one millimeter has 19 been identified by mesh experts as 20 what's needed for a safe mesh. 21 Effective pore size. 22 BY MR. MORIARTY: 23 Q. Okay. I'm just trying to 24 figure out -- let's assume all the same</p>	<p style="text-align: right;">Page 221</p> <p>1 not have had dyspareunia? 2 A. No, that is not my opinion. 3 Q. Okay. So what complication 4 would she not have had with an effective 5 pore size of one millimeter? 6 A. Mrs. Hammons has dyspareunia 7 because of mesh contraction. There are 8 many other causes of dyspareunia that 9 don't apply to Mrs. Hammons. And I can't 10 predict in some future hypothetical 11 whether she would have an experience of 12 one of those other factors. 13 Q. But are you saying that she 14 would not have dyspareunia from mesh 15 contraction had the pore size been 16 different? 17 A. That's my understanding, 18 yes. 19 Q. Okay. Did Dr. Heit ever say 20 in his deposition that it was impossible 21 to remove the mesh that he did remove 22 from Patricia Hammons? 23 A. I'm sorry? It's impossible 24 to remove the mesh he removed?</p>

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<p style="text-align: right;">Page 222</p> <p>1 Q. I knew somebody was going to 2 flag that silly question. 3 MR. MORIARTY: I thought it 4 was going to be you. 5 MR. SLATER: I'm just trying 6 to figure out what happened when 7 you said we were almost done an 8 hour ago. 9 MR. MORIARTY: It's not my 10 fault. 11 MR. SLATER: Now I feel 12 responsible. 13 BY MR. MORIARTY: 14 Q. So, obviously, Dr. Heit was 15 able to remove some of the mesh, correct? 16 A. Yes. 17 Q. Now, did he say in his 18 deposition that he left whatever mesh he 19 left behind because it was impossible to 20 remove? 21 A. Because it -- in his 22 judgment, the risk of continuing to 23 remove the mesh was not in the patient's 24 best interest, not that it was</p>	<p style="text-align: right;">Page 224</p> <p>1 Hospital, which is a emergency room 2 record. Remember you were shown that 3 earlier? 4 A. Yes. 5 Q. And you talked about a 6 complaint of a pessary falling out. Do 7 you remember that question? 8 A. Yes. 9 Q. And I just want to show you 10 on the third page. It says that "she had 11 pain in the vaginal area and the 12 aggravating factor was the pessary" and 13 that "the onset of that pain was this 14 evening," correct? 15 A. Yes. 16 Q. Is there any indication this 17 was anything other than an acute event 18 that caused discomfort? 19 A. No. 20 Q. Okay. I'll start at the end 21 and work my way forward. 22 You were asked about the 23 bidirectional elasticity statement that 24 was in the IFU, even though Ethicon</p>
<p style="text-align: right;">Page 223</p> <p>1 necessarily impossible. He's making a 2 judgment based on his experience about 3 how to proceed in the best interest of 4 the patient. 5 Q. In other words, that the 6 risk of continuing the dissection 7 exceeded the risk of leaving the mesh 8 behind? 9 A. Correct. At that one -- 10 yes, at that setting. 11 MR. MORIARTY: I'm done. 12 Thanks for your patience. 13 MR. SLATER: I have a few 14 cleanup questions. Do you want me 15 to do them now? 16 (Whereupon, a discussion was 17 held off the record.) 18 - - - 19 EXAMINATION 20 - - - 21 BY MR. SLATER: 22 Q. Dr. Weber, you were shown 23 earlier in the deposition a record from 24 February 1, 2007, from Daviess Community</p>	<p style="text-align: right;">Page 225</p> <p>1 eventually admitted they had obviously 2 had no data to support it and removed it 3 for that reason. Do you remember you 4 were asked some questions about that? 5 A. Yes. 6 Q. Just to be clear, and make 7 sure the testimony is clear. Did you see 8 in Dr. Baker's deposition where he said 9 that he believed that statement to be 10 true and supported? 11 A. Yes. 12 MR. MORIARTY: Objection. 13 BY MR. SLATER: 14 Q. And did you see in his 15 deposition that Dr. Baker indicated that 16 was a factor that led him to use the 17 Prolift? 18 MR. MORIARTY: Objection. 19 BY MR. SLATER: 20 Q. You can answer. 21 A. Yes. 22 Q. Okay. If Dr. Baker hadn't 23 used the Prolift, would I be correct that 24 the injuries you've attributed to the</p>

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<p style="text-align: right;">Page 226</p> <p>1 Prolift couldn't have happened because 2 there would have been no Prolift to cause 3 them? 4 A. Correct. 5 Q. The bidirectional elasticity 6 statement actually has a second half that 7 says that it allows adaptations to the 8 body's stresses, correct? 9 A. Yes. 10 Q. And when the mesh contracts 11 and becomes inflexible and hard, it's not 12 adapting to the body's stresses, is it? 13 A. No. 14 MR. MORIARTY: Objection. 15 BY MR. SLATER: 16 Q. So the lack of adaptation to 17 the body's stresses would actually be one 18 of the factors that was causing harm to 19 Mrs. Hammons, wouldn't it? 20 MR. MORIARTY: Objection. 21 THE WITNESS: Yes. 22 BY MR. SLATER: 23 Q. You were asked about the 24 frequency and urgency in relation to</p>	<p style="text-align: right;">Page 228</p> <p>1 counsel about your opinions on future 2 injuries and symptoms she suffered due to 3 the mesh. Do you remember those 4 questions a few minutes ago? 5 A. Yes. 6 Q. And you were asked by 7 counsel would the mesh need to be 8 removed, and you indicated, Well, that 9 would be a conversation she'd have to 10 have with a surgeon that was actually 11 considering treating her, correct? 12 A. Yes. 13 Q. Am I correct that the 14 removal of any large amount of mesh, 15 especially the arms, meaning the mesh 16 that remains in her body, would not 17 likely be safe and certainly not feasible 18 to a large extent, especially taking into 19 account the arms? 20 MR. MORIARTY: Objection. 21 THE WITNESS: Yes. 22 BY MR. SLATER: 23 Q. Early on in the deposition, 24 you were asked about Dr. Baker's</p>
<p style="text-align: right;">Page 227</p> <p>1 whether or not there was some -- well, 2 rephrase. 3 You were asked about the 4 frequency and urgency that's been 5 reported for Ms. Hammons, correct? 6 A. Yes. 7 Q. And am I correct that there 8 were -- there are indications in the 9 records that the mesh was irritating and 10 actually eroding into the detrusor? 11 MR. MORIARTY: Objection. 12 THE WITNESS: Yes. 13 BY MR. SLATER: 14 Q. And is it likely that that 15 is a contributing factor to her frequency 16 and urgency complaints? 17 A. Yes. 18 Q. And is it likely that 19 continued irritation from the mesh and 20 the scarring in that area would be a 21 likely contributing factor to any ongoing 22 frequency and urgency that she has? 23 A. Yes. 24 Q. You were asked about -- by</p>	<p style="text-align: right;">Page 229</p> <p>1 evaluation of the stage of prolapse when 2 he first was evaluating Ms. Hammons. Do 3 you remember those questions from earlier 4 in the deposition? 5 A. Yes. 6 Q. And Dr. Baker -- tell me if 7 I'm correct -- indicated a Stage IV 8 prolapse in his records, correct? 9 A. A Grade 4. 10 Q. Grade 4. Sorry. 11 And his definition of a 12 Grade 4 prolapse -- tell me if I'm 13 wrong -- was that it protrudes outside 14 the vagina at all? 15 A. Outside -- right. Correct. 16 Outside of the hymen, yes. 17 Q. Outside of the hymen. I'm 18 sorry. 19 Under the POP-Q measurement 20 system, which is the rigorous clinical 21 evaluation system, could the bladder 22 protrude outside the hymen, beyond the 23 hymen and be a Stage II? 24 A. Yes.</p>

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<p style="text-align: right;">Page 230</p> <p>1 Q. So is that one of the</p> <p>2 factors that you considered in evaluating</p> <p>3 what her stage of prolapse likely was?</p> <p>4 A. Yes.</p> <p>5 Q. Did you see documents</p> <p>6 internal to Ethicon indicating that the</p> <p>7 Prolift was actually only indicated for</p> <p>8 Stage III and IV prolapse?</p> <p>9 MR. MORIARTY: Objection.</p> <p>10 This is a general opinion.</p> <p>11 MR. SLATER: You asked about</p> <p>12 this. And she said it. I'm going</p> <p>13 to make it clean.</p> <p>14 But that was good. You kept</p> <p>15 a straight face.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Are you familiar with those</p> <p>18 documents?</p> <p>19 A. Yes.</p> <p>20 Q. Did Ethicon warn Dr. Baker</p> <p>21 in any way, to your knowledge, that he</p> <p>22 would need to have a rigorous clinical</p> <p>23 evaluation performed of the prolapse to</p> <p>24 ensure that it was at least a full-blown</p>	<p style="text-align: right;">Page 232</p> <p>1 that at all?</p> <p>2 A. No.</p> <p>3 Q. In terms of evaluating,</p> <p>4 again, what the stage of prolapse was,</p> <p>5 you indicated that Ms. Hammons was able</p> <p>6 to actually -- she commented on what she</p> <p>7 could feel, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Did she also indicate that</p> <p>10 she saw a bit of the bladder, that she</p> <p>11 could see that under certain</p> <p>12 circumstances as well?</p> <p>13 A. Yes.</p> <p>14 Q. And when you put together</p> <p>15 everything that Ms. Hammons said and</p> <p>16 everything Dr. Baker said, you believe</p> <p>17 she had a Stage II, possibly an early</p> <p>18 Stage III?</p> <p>19 A. Yes.</p> <p>20 Q. You were asked a question</p> <p>21 about restrictions on Ms. Hammons when</p> <p>22 she went back to work. Do you remember</p> <p>23 that question earlier?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 231</p> <p>1 Stage III or IV before this procedure</p> <p>2 would be indicated? Was he told that --</p> <p>3 MR. MORIARTY: Objection.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. -- to your knowledge, in any</p> <p>6 of the documents that were available at</p> <p>7 the time?</p> <p>8 A. No.</p> <p>9 Q. Was Dr. Baker -- I'm just</p> <p>10 going to expand it -- advised by Ethicon</p> <p>11 that he would have to make sure that she</p> <p>12 had a clearly defined Stage III or IV</p> <p>13 prolapse as defined by the rigorous</p> <p>14 criteria; otherwise the Prolift should</p> <p>15 not be put in this woman's body? Was he</p> <p>16 given any information to that extent at</p> <p>17 all?</p> <p>18 MR. MORIARTY: Objection.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Was Dr. Baker given any</p> <p>22 indication that the stage of prolapse</p> <p>23 actually mattered in terms of whether or</p> <p>24 not a Prolift was indicated? Was he told</p>	<p style="text-align: right;">Page 233</p> <p>1 Q. Was Ms. Hammons cleared to</p> <p>2 go back to work, according to the</p> <p>3 records, by Dr. Baker?</p> <p>4 A. Yes.</p> <p>5 Q. You were asked about the</p> <p>6 question of whether or not Dr. Baker met</p> <p>7 the internal criteria Ethicon stated they</p> <p>8 had created for surgeons who should use</p> <p>9 the Prolift. Do you remember you were</p> <p>10 asked about that?</p> <p>11 A. Yes.</p> <p>12 Q. And, in fact, are there</p> <p>13 committee opinions from AUGS and other</p> <p>14 organizations that talk about the fact</p> <p>15 that only the most highly skilled</p> <p>16 surgeons should use these types of mesh</p> <p>17 kits?</p> <p>18 MR. MORIARTY: Objection.</p> <p>19 THE WITNESS: Yes.</p> <p>20 MR. SLATER: I don't have</p> <p>21 any other -- oh, I do have a</p> <p>22 couple other questions.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. You were asked about the</p>

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<p style="text-align: right;">Page 234</p> <p>1 2000 date FDA public health notification 2 and asked if that was available, 3 something that could have been available 4 to Dr. Baker. Remember you were asked 5 that? 6 A. Yes. 7 Q. That was certainly available 8 to Ethicon, wasn't it? 9 A. Yes. 10 Q. They knew about it, right? 11 A. Yes. 12 Q. The 2008 -- 2007 ACOG 13 bulletin, you authored that, called these 14 procedures experimental. Was that 15 something that was available to Ethicon? 16 MR. MORIARTY: Objection. 17 THE WITNESS: Yes. 18 BY MR. SLATER: 19 Q. Did Ethicon have the 20 opportunity to warn about all those types 21 of things if they had wanted to? 22 A. Yes. 23 MR. SLATER: I don't have 24 any other questions.</p>	<p style="text-align: right;">Page 236</p> <p>1 the report to find those specific words. 2 Certainly, the issue of selecting the -- 3 I'm sorry -- that Ethicon intended 4 Prolift to be used for advanced stages of 5 prolapse, meaning Stage III and IV, is 6 something that is discussed in my report. 7 Q. Okay. And I understand that 8 that is. What I'm trying to find out is 9 whether you have rendered an opinion 10 previously in your primary report, or 11 even in your report in this case, 12 Exhibit 1, that Ethicon had some duty to 13 go so far as to tell the doctors to be 14 extra careful about the documentation and 15 physical examination of the degree of 16 existing prolapse. 17 A. That would be part and 18 parcel of being a highly skilled, 19 high-volume-performing pelvic 20 reconstructive surgeon, to have the 21 familiarity and experience in doing 22 detailed assessments of women's prolapse. 23 Q. That's not my question. My 24 question is only whether you have written</p>
<p style="text-align: right;">Page 235</p> <p>1 - - - 2 FURTHER EXAMINATION 3 - - - 4 BY MR. MORIARTY: 5 Q. Sorry. He raised a couple 6 new ones. 7 Mr. Slater was just talking 8 about -- something about whether Ethicon 9 needed to warn Dr. -- 10 MR. SLATER: That's not what 11 I said. 12 BY MR. MORIARTY: 13 Q. -- Baker about performing a 14 rigorous assessment of the true stage or 15 grade of prolapse. Do you remember that 16 question that he was just asking? 17 A. That was the theme. I don't 18 think those were the words. 19 Q. Okay. 20 A. But, anyway. 21 Q. Is that an opinion that you 22 wrote somewhere in Exhibit 2, your 23 primary report? 24 A. I would have to look through</p>	<p style="text-align: right;">Page 237</p> <p>1 about this opinion before in either 2 Exhibit 1 or Exhibit 2. 3 MR. SLATER: Objection. 4 That's argumentative. And it 5 mischaracterizes. 6 I'll let Dr. Weber answer 7 again. I think she was very 8 direct on that. 9 You can answer again. 10 THE WITNESS: I thought I 11 understood that you were asking 12 whether I address this issue of 13 being skilled and experienced 14 enough to know how to correctly 15 assess a patient's prolapse and 16 then make any decisions about 17 whether the Prolift is indicated 18 or not. 19 BY MR. MORIARTY: 20 Q. Well, I don't want to 21 characterize what you've previously 22 written. My understanding is that you've 23 written opinions before based on company 24 documents and company witness testimony</p>

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<p style="text-align: right;">Page 238</p> <p>1 that the device was intended to be used 2 by high-volume surgeons. Let's just 3 leave it at that, whether the words 4 "highly skilled" are in those testimony 5 or documents. Okay. That's a separate 6 question. 7 What I'm trying to find out 8 is whether you have previously rendered 9 an opinion before today that a company 10 like Ethicon had to go so far as to 11 basically tell doctors how to stage and 12 grade their patients. 13 MR. SLATER: Objection. 14 That mischaracterizes all the 15 testimony and lack of foundation. 16 You can answer. 17 BY MR. MORIARTY: 18 Q. That's a "yes" or "no" or an 19 "I don't remember if I've written that 20 before?" 21 MR. SLATER: I don't agree 22 with the characterization. The 23 doctor can answer as she sees fit 24 to a question that's very</p>	<p style="text-align: right;">Page 240</p> <p>1 MR. MORIARTY: Okay. I 2 don't have any other questions. 3 (The witness was excused.) 4 (Deposition concluded at 5 approximately 3:08 p.m.) 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 239</p> <p>1 confusing. 2 THE WITNESS: In the very 3 specific way your question is 4 worded, I don't believe I've 5 written on that in my report. 6 BY MR. MORIARTY: 7 Q. Okay. The other thing that 8 Mr. Slater asked you about is, is it your 9 opinion that Mrs. Hammons currently has 10 frequency and urgency related to her 11 Prolift? 12 A. Mrs. Hammons has urinary 13 symptoms related to the fact that the 14 Prolift was implanted and, in the process 15 of scarring and all the things that we've 16 been talking about, affected her bladder 17 function to an ongoing extent, regardless 18 of what small portion of the mesh may be 19 removed and what portion remains. 20 Q. All right. So it's your 21 opinion that Mrs. Hammons has ongoing 22 urinary complaints related to her 23 Prolift? 24 A. Yes.</p>	<p style="text-align: right;">Page 241</p> <p>1 State of Pennsylvania : 2 :SS 3 County of Philadelphia : 4 5 CERTIFICATE 6 I, MICHELLE L. GRAY, a 7 Registered Professional Reporter, 8 Certified Shorthand Reporter and Notary 9 Public do hereby certify that, pursuant 10 to notice, the deposition of ANNE M. 11 WEBER, M.D. was duly taken at Kline & 12 Specter, 1525 Locust Street, 13 Philadelphia, Pennsylvania, on 14 September 1, 2015 at 9:03 a.m. before me. 15 ANNE M. WEBER, M.D. was first duly sworn 16 by me according to law to tell the truth, 17 the whole truth and nothing but the truth 18 and thereupon did testify as set forth in 19 the above transcript of testimony. The 20 testimony was taken down stenographically 21 by me. 22 I do further certify that 23 the above deposition is full, complete 24 and a true record of all the testimony 25 given by the said witness. 26 27 MICHELLE L. GRAY, 28 A Registered Professional 29 Reporter, Certified Shorthand 30 Reporter and Notary Public 31 Dated: September 2, 2015 32 33 (The foregoing certification 34 of this transcript does not apply to any 35 reproduction of the same by any means, 36 unless under the direct control and/or 37 supervision of the certifying reporter.) 38 39 40 41 42 43 44</p>

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<div style="text-align: right;">Page 242</div> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<div style="text-align: right;">Page 244</div> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, 1 - 245, and that the</p> <p>6 same is a correct transcription of the</p> <p>7 answers given by me to the questions</p> <p>8 therein propounded, except for the</p> <p>9 corrections or changes in form or</p> <p>10 substance, if any, noted in the attached</p> <p>11 Errata Sheet.</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16 _____</p> <p>17 ANNE M. WEBER, M.D. DATE</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>Subscribed and sworn</p> <p>to before me this</p> <p>_____ day of _____, 20____.</p> <p>My commission expires: _____</p> <p>Notary Public</p>
<div style="text-align: right;">Page 243</div> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 _____</p>	<div style="text-align: right;">Page 245</div> <p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p>